

# **Roles for pharmacists in improving the quality use of psychotropic medicines in Residential Aged Care Facilities**

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## **DECLARATION OF ORIGINALITY**

This thesis contains no material which has been accepted for the award of any other degree or diploma by the university or any other institution, except by way of background information and duly acknowledged in the thesis. To the best of my knowledge and belief, this thesis contains no material previously published or written by another person except where due acknowledgement is made in the text of the thesis, nor does the thesis contain any material that infringes copyright.

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## **ABSTRACT**

The major psychotropic drug classes are antipsychotics, antidepressants and anxiolytic/hypnotics. Professional guidelines advise that these agents should only be prescribed to manage behavioural and psychological symptoms of dementia (BPSD), anxiety and insomnia in older people after non-drug measures have proved ineffective. Psychotropic medications, particularly antipsychotics and benzodiazepines, are associated with significant risks, yet they only offer modest benefits to treat these conditions. Consequently, these medications should be initiated at the lowest effective dose, monitored regularly and administered for time-limited periods. Despite this advice, many researchers have reported high rates of psychotropic drug use in Residential Aged Care Facilities (RACFs) both in Australia and internationally over the last three decades. Moreover, rates of psychotropic use in RACFs appear to be increasing, a trend which most likely reflects the growing proportion of residents with mental health conditions.

The main focus of this thesis was on antipsychotic and benzodiazepine use as the prescribing of these particular psychotropic agents is widespread, there are doubts over their effectiveness and they are strongly associated with significant risks in older people. There has also been considerable attention from both professional and regulatory authorities directed at rationalising the use of these medications. Although antidepressants are also associated with risks, there is strong evidence for their effectiveness in this population and many experts in the psychogeriatric field feel they are underutilised in the RACF setting. For this reason, the research was targeted at promoting guideline-based use of antipsychotics and benzodiazepines.

Aside from their traditional supply role, pharmacists are increasingly becoming involved in promoting Quality Use of Medicines or 'QUM'. In Australia, at the time of this research, community pharmacies were funded to provide Residential Medication Management Reviews (RMMRs) and associated QUM strategies to each facility, such as medication audit, formulary development and nurse education. Although RMMRs were shown to improve medication use in one large controlled trial, the effect of pharmacist-led QUM strategies on RACF psychotropic prescribing has not been evaluated. Therefore, the key objective of this thesis was to assess if pharmacists could positively influence RACF psychotropic utilisation through the use of a series of facility-focused QUM strategies delivered in a dedicated intervention project.

However, before the intervention project could be developed, some vital background research was required. This is why the research for this thesis was conducted in three chronological stages. An evaluation of current psychotropic usage was initially needed to identify the main areas of concern and gauge the overall pattern of prescribing; thus, the first stage involved a retrospective cross-sectional study of prescribing data in a large representative sample of 40 RACFs throughout



Tasmania. As professional guidelines recommend that psychotropic medications are reviewed on a regular basis and dose reductions attempted routinely, the cross-sectional measure was repeated 12 months later to evaluate the extent of review in the RACFs.

Previous studies had shown a high rate of psychotropic use in Tasmanian RACFs. This trend was also evident in this study, with an average of 42% of residents taking regular doses of benzodiazepines and 20% of residents taking antipsychotics during 2006. Although the rate of antipsychotic prescribing was similar to rates reported in Sydney and New Zealand in the same time frame, the rate of benzodiazepine use in Tasmania was three times that reported in these other studies. Further, when the RACFs were re-audited a year later, over 60% of antipsychotic and benzodiazepine medications and doses were unchanged; a finding which strongly implies a lack of review of these psychotropic agents, contrary to current professional guidance.

After obtaining an overall picture of prevalence, inappropriateness and the extent of review of antipsychotics and benzodiazepines, the second stage of this research thesis sought to gain a greater understanding of the determinants underlying their use in RACFs. A qualitative approach involving thematic analysis of semi-structured interviews with health professionals and relatives was chosen to answer the key research questions of this second stage, including why these medications are used and who is influencing their initiation and review? As there is a paucity of qualitative research related to psychotropic use in the residential aged care setting, this study not only provided valuable insight but also strongly informed the methodology of the subsequent intervention project.

It became evident that many health professionals had limited knowledge about the risks associated with psychotropic use in older people, and that reviews were conducted infrequently, if at all. Of all health professionals, nursing staff were the most influential when psychotropic medications were initiated and utilised. As a consequence of this qualitative research, the key strategies of the intervention project were primarily targeted at nursing staff and designed to offer feedback on psychotropic use to individual RACFs, provide education about the risks associated with these agents, promote professional guidelines and encourage regular review and dose reduction.

The main objective of the thesis was to design, conduct and evaluate an intervention project, trialling QUM strategies provided by community pharmacists, to facilitate the quality use of antipsychotic and benzodiazepine medications in RACFs. This third and final stage involved a large controlled trial run in 25 RACFs in the two major cities of Tasmania and was termed the 'Reducing Use of Sedatives' (RedUSE) project. Thirteen Hobart RACFs were recruited as the intervention group, with 12 Launceston RACFs acting as the control group.

The RedUSE intervention was run over six months during 2008 to 2009. A series of QUM strategies were offered in the intervention RACFs, including two dedicated psychotropic medication audits, nurse education and feedback, and an interdisciplinary sedative review process.

At the conclusion of the project, the prevalence of benzodiazepines was significantly reduced in intervention facilities (31.8% to 26.9%,  $p < 0.005$ ), whereas a small non-significant increase in use was found in control homes. Likewise, antipsychotic use was significantly reduced in intervention facilities when compared to control facilities, although to a lesser extent than benzodiazepines (20.3% to 18.6%,  $p < 0.05$ ). Over the six months of the intervention project, the proportion of dose reductions of both benzodiazepines and antipsychotics in intervention facilities was almost double the proportion recorded in control facilities.

Although several intervention projects aimed at improving RACF psychotropic use have been published, few research teams have reported cost effectiveness data, clinical outcomes for residents or evaluated the sustainability of the intervention project over the long term. Consequently, various post-analyses of intervention data were conducted to evaluate the clinical impact of the project on residents in terms of falls and behaviour, and assess cost effectiveness. In order to determine the sustainability of the intervention, a final follow-up audit measure was performed 12 months after the project was completed.

The post analyses indicated that the reduction in sedative use had limited impact on falls; however, there was a significant decrease in challenging behaviours in those facilities recording a significant reduction in antipsychotic use. Some cost savings were achieved resulting from the reduction in benzodiazepine prescribing, but savings were not observed in antipsychotic costing. Finally, the repeat 12-month audit measure demonstrated that the reduction in benzodiazepine use in the intervention RACFs was sustained, with the mean daily dose of benzodiazepines continuing to reduce even further. In contrast, RACF antipsychotic use returned to pre-trial levels and doses remained static.

The RedUSE intervention led to a statistically significant reduction in the proportion of residents in RACFs receiving benzodiazepines and antipsychotics, and the number of dosage reductions of these agents in intervention facilities was double that reported in the control facilities. These findings suggest that QUM strategies coordinated through community pharmacies, and incorporating the dissemination of local data on medication use, offer an effective approach to reduce antipsychotic and benzodiazepine use in RACFs.

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## LIST OF PUBLICATIONS

*All publications listed resulted from work described in this thesis.*

### **Peer-reviewed journal publications**

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Westbury J, Peterson G, Jackson S. An effective approach to reduce antipsychotic and benzodiazepine use in aged care homes: the RedUSE project. 8<sup>th</sup> National Conference of Emerging Researchers in Ageing. Melbourne, October 2009.

Westbury JL. An effective approach to reduce antipsychotic and benzodiazepine use. The combined 2009 conference of the RANZCP Faculty of Psychiatry of Old Age and the APS psychology of Ageing Interest Group. Bond University. Gold Coast, November 2009.

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Westbury J, Robinson A, Peterson G. Why are psychotropic medications prescribed in aged care homes to manage behaviours of concern and whose role is it when these medications are initiated and reviewed? IPA 15<sup>th</sup> International Congress. Den Hague, the Netherlands, September 2011.

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## **ABBREVIATIONS**

AACP	Australian Association of Consultant Pharmacists
ABC	Antecedent-Behaviour-Consequence
ADAS-Cog	Alzheimer's Disease Assessment Scale - Cognitive
ADL	Activities of Daily Living
AGFI	Aged Care Funding Instrument
AIHW	Australian Institute of Health and Welfare
AOR	Adjusted Odds Ratio
APA	American Psychiatric Association
APAC	Australian Pharmaceutical Advisory Council
ATC	Anatomical Therapeutic Chemical
BEHAVE-AD	Behavioural pathology in Alzheimer's Disease
BLT	Bright Light Therapy
BPSD	Behavioural and Psychological Symptoms of Dementia
CATIE-AD	Clinical Antipsychotic Trial of Intervention Effectiveness
CBT	Cognitive Behavioural Therapy
CI	Confidence Interval
CMAI	Cohen-Mansfield Agitation Index
CNS	Central Nervous System
CPE	Continuing Professional Education
CSM	Committee on Safety of Medicines
CVAE	Cerebrovascular Adverse Events
DBI	Drug Burden Index
DCM	Dementia Care Mapping
DON	Director Of Nursing
DUE	Drug Use Evaluation
DSM-IV-TR	Diagnostic and Statistical Manual of the American Psychiatric Association - fourth edition - Text Revision
ECG	Electrocardiogram
EN	Enrolled Nurse
EPS	Extra Pyramidal Symptoms
FDA	Federal Drug Administration
GABA	Gamma-Amino Butyric Acid

GAD	Generalised Anxiety Disorder
GAI	Geriatric Anxiety Inventory
GP	General Practitioner
ICD-10	International Classification of Diseases - 10th version
IPA	International Psychogeriatric Association
MAC	Medication Advisory Committee
MAI	Medication Appropriateness Index
MATES	Veterans Medication Advice and Therapeutics
M	Mean
<i>Med</i>	Median
MED	Minimum Effective Dose
MMSE	Mini Mental State Examination
MSS	Multi-Sensory Stimulation
NDB	Need-driven Dementia-compromised Behaviour
NICE	National Institute for Clinical Excellence
NPI	Neuropsychiatric Inventory
NPS	National Prescribing Service
OBRA-87	Omnibus Budget Reconciliation Act of 1987
OAMHP	Old Age Mental Health Psychotropic
PAT	Psychotropic Assessment Tool
PBS	Pharmaceutical Benefits Scheme
PCA	Personal Care Assistant
PhARIA	Pharmacy Access Remoteness Index of Australia
PHARM	Pharmaceutical Health and Rational Use of Medicines
PIM	Potentially Inappropriate Medication
PLM	Periodic Limb Movements
PRN	when required
PSA	Pharmaceutical Society of Australia
PSG	Polysomnography
QOL	Quality of Life
QUM	Quality Use of Medicines
RACF	Residential Aged Care Facility
RANZCP	Royal Australian and New Zealand College of Psychiatry
RCT	Randomised Controlled Trial
RedUSE	Reducing Use of Sedatives
REM	Rapid Eye Movement
RLS	Restless Legs Syndrome

RMMR	Residential Medication Management Review
RN	Registered Nurse
SCN	Suprachiasmatic Nucleus
SCT	Stimulus Control Therapy
SD	Standard Deviation
SDB	Sleep Disordered Breathing
SDD	Standardised Daily Dose
SNRI	Serotonin Noradrenaline Reuptake Inhibitor
SSRI	Selective Serotonin Reuptake Inhibitor
SR	Sleep Restriction
TCA	Tricyclic Antidepressant
TIA	Transient Ischaemic Attack
UTI	Urinary Tract Infection
WHO	World Health Organisation

## **PART ONE: THE TREATMENT OF MENTAL HEALTH CONDITIONS IN OLDER PEOPLE**

### **Introduction**

## **CHAPTER ONE: AN OVERVIEW OF OLD AGE MENTAL HEALTH AND RESIDENTIAL AGED CARE**

### **1.1 The ageing population and mental health**

The population in Australia is ageing rapidly. In 2007, there were 2.4 million people aged 65–84 years.<sup>1</sup> By 2022 there will be approximately 4 million Australians in this age group and this figure is expected to rise to approximately 6.4 million by 2056.<sup>2</sup> The largest projected increase in the population, however, will occur in the number of people aged 85 years and over, with this cohort predicted to rise from 344 000 in 2007 to 1.7 million in 2056.<sup>1</sup>

It is estimated that over a quarter of adults over 65 years will experience a mental health condition, with dementia, anxiety and depression the most prevalent of the so called ‘psychogeriatric’ disorders.<sup>3</sup> ‘Sleep disorder’ commonly presents as a symptom of these three disorders but is also classified as a mental health condition in its own right.<sup>4</sup> Over the coming years the number of older people with mental health conditions is predicted to rise dramatically.<sup>5</sup> To illustrate, in 2010, the number of Australians with dementia exceeded 255 000, and it is projected that by 2050, the number of dementia cases will exceed 980 000.<sup>6</sup>

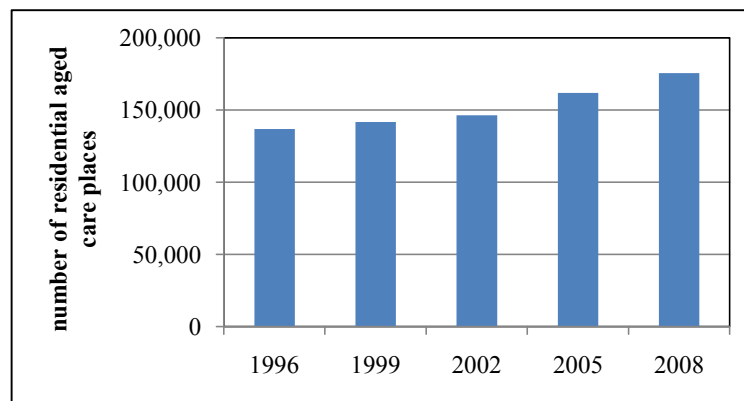
Aside from population ageing there are several reasons why the prevalence of old age mental health conditions is increasing. With improved treatment of physical conditions and more effective treatment for psychiatric illnesses, the high mortality in mentally ill young adults is expected to decrease, resulting in a greater number of those who will reach old age.<sup>7</sup> Furthermore, ageing baby boomers (people born between 1946 and 1964) are expected to have a higher risk for anxiety and depression than the current cohort of older people.<sup>7</sup> Finally, a greater number of ageing-related physical conditions and disabilities in the ageing population will inevitably give rise to a higher number of psychological problems.<sup>8</sup> Reasons such as these led a group of prominent American old age psychiatrists to release a consensus statement warning that the number of older people with mental health conditions will more than likely double in the next 20 years.<sup>7</sup>

### **1.2 Residential Aged Care in Australia**

With the growth of the older population, the number of people receiving care in Residential Aged Care Facilities (RACFs) has also been rising steadily (Figure 1).<sup>9</sup> Although only a small proportion of Australians over 65 years will live in RACFs at any one time (approximately 6%), the lifetime probability of utilising such care is increasing, along with the average lifespan.<sup>10,11</sup> Projections suggest that 43% of all Australians who reach 75 years of age will spend some portion of their remaining years in an RACF.<sup>10</sup>



**Figure 1: Number of RACF places, Australia, 1996-2008.<sup>9</sup>**



As of the end of June 2009, there were 2 783 mainstream RACFS in Australia providing a total of 175 225 places, an increase of over 2500 places from mid-2008.<sup>9</sup> In contrast, the number of RACFs has gradually declined over the last decade as facilities increase in size, with the average number of places per facility increasing from 46 to 63 from 1998 to 2009.<sup>9</sup> Nationally, residential aged care services are delivered across a range of sectors, including private, government (local and state government), and not-for-profit (comprising religious, community-based, and charitable) providers. Not-for-profit and private organisations were the main providers of residential aged care services in Australia across all states and territories in 2008/9 (60% and 29% respectively).<sup>9</sup>

In an attempt to contain demand on the residential care system, the Commonwealth Government has introduced a variety of supported alternatives such as ‘Extended Aged Care at Home’ and ‘Community Aged Care Packages’ which aim to enable older people to remain in their own homes.<sup>10,11</sup> However, there are factors influencing the increased demand for residential aged care places which are difficult to control, including increasing numbers of highly dependent older people who cannot function effectively at home and a reduction in the number of potential carers.<sup>10</sup> As a consequence, the demand for RACF places in Australia will continue to rise. In fact, a recent report has predicted a national shortage of at least 10 000 RACF beds by 2030.<sup>6</sup>

### **1.3 The dependency level of residents in RACFs**

The demographic mix of residents in RACFs has altered markedly over the last decade. The 2008/2009 Australian Institute of Health and Welfare (AIHW) ‘Residential Aged Care in Australia’ report notes that residents are becoming older and more infirm.<sup>9</sup> In June 2009, over half (55%) of residents were aged over 85 years of age and 27% were aged over 90 years; figures significantly higher than those recorded in June 2000 (i.e. 50% of residents over 85 years of age and 23% of residents aged over 90 years).<sup>9</sup> In 2009, three-quarters (75%) of

residents were classified as requiring ‘high care’ using the Aged Care Funding Instrument (ACFI).<sup>9</sup> By comparison, only 10 years ago the proportion classified as ‘high care’ was 58%, representing a marked escalation in the dependency levels of residents.<sup>9,11</sup> Further evidence that the majority of residents of Australian RACFs require a high level of personal care and assistance comes from the 2007 AIHW ‘Older Australians at a glance’ report (Table 1).<sup>11</sup> This report lists the type of assistance needed and reveals an increasing proportion of residents requiring assistance for psychological and behavioural symptoms such as verbal outbursts (54%), wandering (32%) and physical aggression (26%); all symptoms of mental health disorders.<sup>11</sup> To sum up, an increasing number of Australians will be placed in RACFs which have become the locations wherein the most impaired, dependent and mentally ill older people will reside.

**Table 1: Permanent aged care residents, need for at least some assistance for selected dependency items, June 1999 to June 2006. (%)<sup>11</sup>**

Type of assistance	1999	2000	2001	2002	2003	2004	2005	2006
Communication	90.8	91.6	93.0	93.7	94.4	95.1	95.6	96.1
Personal hygiene	92.2	92.8	93.2	93.4	93.7	94.2	94.4	94.6
Understanding and undertaking living activities	83.2	85.1	86.3	87.0	87.6	88.5	89.3	89.7
Mobility	82.8	82.9	83.5	83.7	84.2	84.6	84.7	85.5
Meals and drinks	75.9	75.5	76.5	76.5	77.3	78.5	79.1	79.1
Bowel management	67.5	73.1	77.2	80.3	82.7	85.1	87.3	88.2
Bladder management	64.5	65.9	67.2	67.0	67.8	68.4	68.9	69.4
Toileting (assistance)	68.0	67.6	68.1	67.5	67.8	68.7	69.4	70.1
Problem wandering or intrusive behaviour	29.4	29.5	29.2	29.2	29.9	30.6	31.3	31.7
Verbally disruptive or noisy	46.1	50.7	50.3	50.3	50.5	51.3	52.4	53.5
Physically aggressive	30.2	26.6	26.1	25.9	25.6	25.7	26.0	26.1
Emotional dependence	61.2	68.2	66.4	63.6	63.2	64.3	64.8	65.5
Danger to self or others	53.7	56.9	58.0	58.0	59.4	61.4	63.4	64.8

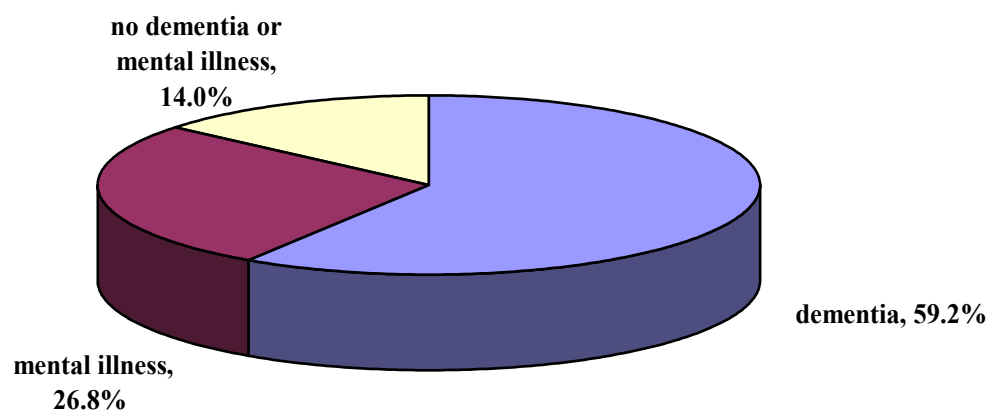
Source: AIHW analysis of DoHA Aged and Community Care management Information System (ACCMIS) database.

#### **1.4 Mental health in RACFs**

Researchers such as Rovner and Katz have referred to RACFs as, ‘*modern mental institutions for the elderly*’, as they are places with a high prevalence of psychiatric symptomatology and widespread prescription of psychotropic drugs.<sup>10,12</sup> The rise in mental health conditions in RACFs is impacted by factors other than just altered ageing demographics and increasing rates of dementia. The deinstitutionalisation of mental health care with the resultant closure of many long-stay psychiatric hospital beds, and an increasing focus on short-term acute admissions to hospital has also contributed to RACFs providing care to a greater number of people with mental health disorders.<sup>13</sup>

The majority of people in RACFs have some form of underlying primary brain disease, with dementia the most common of these disorders.<sup>14</sup> Several researchers from Australia, Norway and Finland have assessed dementia incidence in large samples of RACF residents by testing residents with validated scales, reporting a surprisingly consistent incidence of 76-81%.<sup>15-17</sup> It is, however, difficult to get an accurate prevalence measure of dementia as the condition is often poorly documented or diagnosed.<sup>10,18,19</sup> When Selbaek *et al.* assessed 1163 Norwegian RACF residents with the Neuropsychiatric Inventory (NPI)(see Appendix A), 80.5% of residents were found to have dementia, yet only 55% of these residents had a diagnosis of dementia recorded in their medical records.<sup>17</sup> In the latest AIHW report on residential aged care, almost 60% of residents were diagnosed with dementia. What is more surprising is the small proportion of residents (14%) classified as not having an old age mental health condition (Figure 2). Although it should be noted that a mental health classification was ‘missing’ in 12% of the resident sample.<sup>9</sup>

**Figure 2: Diagnosed dementia/mental illness for Australian RACF residents: June 2009.<sup>9</sup>**



Aside from dementia, depression and anxiety are also prominent in RACFs (Table 2 lists both the international and national RACF incidence of mental health conditions).<sup>2</sup> Anxiety has a reported incidence of between 10-20% in the community, whereas the prevalence of anxiety in RACFs is thought to approach 40%.<sup>20-22</sup> Symptoms of depression occur in approximately 15% of older people in the general community and the prevalence rate for major clinical depression is thought to be 2-4%.<sup>14</sup> In contrast, the average incidence of depression in Australian RACFs exceeds 40% of residents, with studies signifying that between 15-25% suffer from major clinical depression.<sup>3,14,15</sup> Although other mental disorders, including schizophrenia and bipolar disorder, are not as common in RACFs as other conditions, they are still found at higher rates

than in the community.<sup>2,23</sup> An analysis of General Practitioner (GP) consultations at RACFs found that schizophrenia was managed at twice the rate in RACFs compared to all usual GP encounters.<sup>24</sup>

**Table 2: Incidence of mental health conditions in International and Australian RACF studies (%)**<sup>15,17,25-28</sup>

<b>Mental health condition</b>	<b>International incidence</b>	<b>Australian incidence</b>
Dementia	75-81	78
Depression	30-42	42
Anxiety	29	11-25
Schizophrenia	4-8	6
Bipolar disorder	6	?

### **1.5 Barriers to the diagnosis of mental health disorders in RACFs**

In a recent Federal government report on residential care and people with psychogeriatric disorders, the importance of formal assessment and diagnosis of mental health conditions was stressed as '*fundamental for ensuring good care*'.<sup>13</sup> For the majority of residents, nursing staff and GPs will be the first point of contact for management when these behavioural and psychological symptoms appear or escalate. Accordingly, these health professionals will be expected to diagnose and manage these symptoms. However, it is well recognised that training on the recognition of mental health disorders for RACF nursing staff is inadequate.<sup>29,30</sup> For instance, in a recent survey of 320 Australian aged care staff, 71% of care staff and 63% of registered nurses had not received any training on depression. Access to GPs, too, is problematic and like nursing staff, there is potential to strengthen GP skills in the diagnosis and management of psychiatric and behavioural disorders in older people.<sup>13,31</sup> This was demonstrated in a large Australian study which found that GPs did not recognise mental disorders in 56% of their patients, especially those presenting with largely somatic symptoms.<sup>32</sup>

### **1.6 Mental health care expertise in RACFs**

One of the paradoxes of aged care is that despite the predominance of old age mental health conditions and predictions of an increase in their prevalence, RACFs are not adequately funded or staffed to provide effective mental health care.<sup>2,14</sup> Psychiatric conditions are often unrecognised but even when diagnosed, only a small percentage of residents with mental health conditions receive care from mental health professionals.<sup>14,33</sup> Medicare data indicate that people over 65 years have about a third the chance of receiving a specialist psychiatric consultation compared to younger adults.<sup>34</sup>

Ironically, while dependency levels and the incidence of psychogeriatric conditions in RACFs have increased markedly over the last decade, there has been a decline in the number of Registered and Enrolled Nurses (RNs and ENs) working in the sector.<sup>2</sup> For example, between

2003 and 2007, total employment of RNs in Australian RACFs fell by approximately 1 600 to 22 400.<sup>35</sup> Indeed, much of the front-line care within RACFs is typically done by Personal Care Assistants (PCAs) who are often on low wages and who have limited professional training.<sup>2,10</sup> Another issue is a high workforce turnover, with one in five nurses and a quarter of PCAs having to be replaced every year.<sup>35</sup>

A major factor influencing mental health care in RACFs is that the number of GP attendances has been decreasing over recent times due to factors such as workforce shortages, high workloads, and part-time work preferences.<sup>36</sup> This means that nursing staff at facilities are often required to manage their residents' mental health symptoms.<sup>10</sup> Yet, many of the nursing staff in RACFs are not knowledgeable about the nature of psychological and behavioural symptoms experienced by their residents, they seldom seek appropriate mental health referrals once a problem is recognised and many lack training in both non-pharmacological and pharmacological management of mental health conditions.<sup>10</sup> These deficits in staffing, GP coverage and training in old age mental health, combined with increasing numbers of residents with complex behavioural and psychological symptoms, mean the management of mental health conditions in RACFs may be less than ideal.

## **CHAPTER TWO: QUALITY USE OF MEDICINES IN RACFS**

### **2.1 Quality use of medicines in RACFs**

Factors such as workforce shortages, high workloads and a lack of training on medication-related issues also impact on other aspects of RACF medical care besides mental health management. Residents are often users of multiple medications and are also considered at high risk of medication-related problems, including adverse drug reactions.<sup>37</sup> Over the last twenty years there has been considerable attention focused on improving the quality of RACF medication use. The main drivers of this change were a series of formal enquiries into health and pharmaceuticals in the late 1980's and 1990's in which a range of medication-related issues for residents of RACFs were revealed.<sup>37</sup> For example, one important enquiry was conducted by a NSW Ministerial Taskforce in response to a landmark study by Professor John Snowdon *et al.* in 1995, which reported alarmingly high levels of benzodiazepine and antipsychotic use in a large sample of Sydney RACFs.<sup>38</sup> In its 1997 report entitled 'Psychotropic Medication Use in Nursing Homes', the NSW Taskforce not only provided a thorough overview of the issue but recommended strategies to ensure appropriate practice.<sup>39</sup> Some of these strategies included the implementation of multidisciplinary Medication Advisory Committees (MACs) in each RACF, and regular medication reviews and nurse education, both conducted by pharmacists.<sup>39</sup>

Awareness regarding the need to improve Quality Use of Medicines (QUM) in Australia was heightened in the late 1980's by consumer groups and the World Health Organisation (WHO) who called for all its member states at this time to establish national medicinal drug policies.<sup>37</sup> The Australian Federal government responded by forming two pivotal bodies; the Pharmaceutical Health and Rational Use of Medicines (PHARM) committee, and the Australian Pharmaceutical Advisory Council (APAC), to resolve issues concerning medicines.<sup>37</sup> Although both bodies were multidisciplinary in composition, they differed in function. The PHARM committee provided advice around QUM research and developed the 'National Strategy for Quality Use of Medicines', whereas APAC became a vehicle for implementation of policy, providing advice to the Federal Government on a wide range of medicine issues.<sup>37</sup> These two bodies were largely responsible for the development of Australia's 'National Medicines Policy', released in 2000. The overarching aim of the 'National Medicines Policy' was to meet medication and related service needs, so that both optimal health outcomes and economic objectives were achieved.<sup>40</sup> The 'National Medicines Policy' document led directly to the development of the 2002 'National Strategy for Quality Use of Medicines Policy'.<sup>41</sup> Relevantly, many of the recommendations of the NSW Taskforce on 'Psychotropic Use in Nursing Homes', including pharmacist-led medication review and medication education provision, were prioritised in this policy document.<sup>37,39,41</sup>

## **2.2 The RMMR program**

Owing to increased Government, professional and consumer awareness around QUM issues, several key research projects to develop and evaluate new medication services in RACFs were funded through the ‘QUM Evaluation Program’ which was coordinated by the PHARM Committee in the late 1990’s.<sup>37</sup> One pioneering trial conducted by Roberts *et al.* in 52 RACFs in south-east Queensland and north-east NSW found that the combination of pharmacist-led medication review and nursing staff education offered the potential to significantly reduce inappropriate medication use, including that of benzodiazepines, and generate significant cost savings at the same time.<sup>42</sup> Key recommendations arising from Roberts *et al.*’s study included the need for regular medication review and the establishment of MACs in RACFs.<sup>42,363</sup> The findings of this study and other similar studies led the Australian Federal Government to fund community pharmacist-led Residential Medication Management Reviews (RMMRs) in RACFs, starting from 1997. In conjunction with funding, an accreditation process for pharmacists to deliver medication management services in RACFs was developed by the newly formed Australian Association of Consultant Pharmacists (AACP).

A RMMR service is defined as: ‘*a comprehensive medication review, by an accredited pharmacist, that is resident focused involving the systematic evaluation of the resident’s complete medication regimen and management of that medication*’<sup>43</sup> RMMRs ensure QUM by performing the following functions:

- Identification of medication-related problems
- Minimising adverse drug effects and interactions
- Working with prescribers with drug selection, dosing and monitoring
- Improving quality of life
- Encouraging collaboration between pharmacists, GPs and other members of the health care team; and
- Reducing health care costs.<sup>43</sup>

At the same time as the RMMR program was developed, APAC established a working party on QUM in Nursing Homes and Hostels to develop recommendations for improving the medication related issues and associated outcomes for residents of RACFs.<sup>37</sup> Building on existing work by representative GP, nursing and Pharmacy organisations, this working party adopted a multidisciplinary approach, involving all key health professionals and organisations in their ‘Guidelines for Medication Management in Residential Aged Care Facilities’ which were released in 2002.<sup>44</sup>

In 2001, the Federal Government introduced national ‘Standards for Aged Care Facilities’ which reflect the quality management and services expected in RACFs.<sup>45</sup> These standards

determine a RACF's suitability for accreditation by the Aged Care Standards and Accreditation Agency.<sup>46</sup> Due to its multidisciplinary composition and effective lobbying, APAC was able to facilitate the institutionalisation of the 'Guidelines for Medication Management in Residential Aged Care Facilities' through the accreditation standards. One of the accreditation standards directly relates to medication management: The specific criteria are that policies and practices in each RACF provide:

- Safe administration and storage of medications;
- Incident reporting mechanisms;
- Appropriate medication ordering systems; and
- Medication review by appropriate health professionals.<sup>46</sup>

Although the accreditation standards do not specify exact levels or stipulate appropriate psychotropic use, they do include key outcomes on medication management, sleep and behaviour management.<sup>46,47</sup>

### **2.2.1 Evaluation and refinement of the RACF RMMR program**

After its first year of operation an evaluation of the RMMR program was undertaken to examine the effectiveness and outcomes of the service.<sup>48</sup> The evaluation showed high uptake of the service and a positive response from nursing staff, GPs and pharmacists. One important outcome was that GPs reported that the service was more effective if they developed "an effective professional relationship with the accredited pharmacist".<sup>48</sup> As a result of this evaluation, and negotiations with the Federal Government as part of the Pharmacy Guild's Fourth community pharmacy agreement, collaborative RMMRs were introduced in 2007. This type of RMMR involves an interdisciplinary medication review where comprehensive information about the resident and their medicine use is obtained from the resident's GP, and the pharmacist and GP work together to review a resident's medication use.<sup>46</sup> Collaborative RMMRs are available to new residents on admission and for continuing residents on an 'as required' basis, with a maximum of one funded RMMR per 12 month period, except where there has been a significant change in medical condition or medication regimen.<sup>46</sup> A collaborative RMMR must include a referral by a GP, which should identify any potential medication-related problems or clinically relevant issues.<sup>46</sup> From October 2011, as a part of the Pharmacy Guild's Fifth community pharmacy agreement, all RMMRs must now follow the collaborative model.<sup>43</sup>

Having established models and guidelines for medication management in RACFs, barriers to their implementation were identified and recommendations to address them have been proposed after a series of evaluations over the past decade.<sup>37</sup> In spite of some limitations,



the RMMR program has been generally well received and widely adopted by Pharmacies and Pharmacists, with over 80% of Australian residents provided with a RMMR in 2001. Nearly half of the community pharmacies were registered to provide medication review services and almost 10% of pharmacists in Australia were accredited to provide RMMRs in 2001.<sup>37</sup>

### **2.3 RACF QUM strategies**

Although medication review offers the ability to foster QUM at an individual resident level APAC also recognised that quality medicines use was also influenced at the facility level.<sup>49</sup> It was thought that pharmacists could offer a key role in promoting overall QUM in RACFs through various services such as establishing policies and procedures for medication use and other QUM services.<sup>46</sup> Specifically, QUM facility-focused services assist the RACF to provide optimum care as well as maintaining appropriate medication use processes, whereas RMMRs focus on ensuring residents receive appropriate therapy and monitoring.<sup>46</sup> While the two streams are interdependent, they influence each other. A selection of the following QUM services should be provided to the RACF in accordance with a service agreement:<sup>46</sup>

- Drug Use Evaluation (DUE) also known as a medication audit;
- Advice on medicines to members of the health care team;
- MAC participation;
- Guideline development;
- Policy and procedure development;
- In-service education for nursing staff, carers or residents;
- Newsletter provision;
- Assist RACFs to meet accreditation standards;
- Assessment of residents to self-administer;
- Stock management; and
- Participate in Quality Improvement initiatives.

In 2002, pharmacy-led QUM services, including strategies such as nursing education and medication audit and feedback cycles, designed to ensure appropriate use of medication in RACFs, were recommended by APAC and incorporated into the existing RMMR program.<sup>49,50</sup> Five years later, in 2007, as part of the Fourth community pharmacy agreement, an emphasis and increased accountability was applied to these services.<sup>50</sup> To be funded, the provider of RMMRs must now negotiate a set of QUM services, as well as the frequency of these services, with the RACF itself and ensure that these quality improvement activities are conducted.<sup>50</sup> The situation was modified yet again in late 2011.<sup>43</sup> As part of the Fifth community pharmacy agreement, RMMRs and QUM services are now parted and payment is made separately for both

types of services. Unlike RMMRs, QUM services can be provided by a pharmacist who is not accredited.<sup>43</sup> Pharmacists can only be funded for QUM services if they hold a valid service agreement with an individual RACF.<sup>43</sup>

Several RACF research projects in the early 2000's trialled multidisciplinary case conferences involving GPs, medical specialists, senior nursing staff and other health professionals and occasionally, the resident or their carer.<sup>51,52</sup> The case conference format was well accepted by participants and associated with an improvement in medication use outcomes.<sup>51,52</sup> Case conferencing was introduced as an funded Medicare enhanced primary care service item for GPs in 2004, although it should be noted that other health professionals involved, including pharmacists and nursing staff, are unable to claim funding from the government for participation in a RACF case conference.<sup>53,54</sup>

### **2.3.1 Evaluation of QUM services**

A recent evaluation of the current Australian QUM system was conducted by Campbell consulting in 2010.<sup>55</sup> Although QUM services were generally well received, it was noted that some directors of nursing were '*almost entirely unaware of what they could and indeed, should, anticipate from the pharmacist and what services they could request*'. This lack of awareness was theorised to account for a poor provision of QUM service in some facilities.<sup>55</sup>

Another issue involves the exact type of QUM service/s delivered to the RACF. One important role for pharmacists suggested as a 'QUM' activity for RACFs is the provision of education about medication to nursing staff and other members of the health care team. In the Campbell evaluation a marked discrepancy was found between what pharmacists said they provided and the nursing perception of provision. When pharmacists were surveyed, over 80% said they had provided in-service educational sessions for disease state management to a RACF in the last 12 months. However, when nursing staff were surveyed, over a quarter of RACFs had not received any in-service education from pharmacists throughout this period, and in rural areas this figure was significantly higher.<sup>55</sup> It appears that a substantial proportion of RACFs may be missing out on the beneficial QUM service of pharmacist-led educational sessions.

Some additional barriers to QUM in RACFs noted in evaluations were poor knowledge of professional therapeutic guidelines, issues with care transfer between hospitals, community and RACFs, staffing levels and training, and integration of services. MACs proved to be one mechanism to resolve some of these barriers.<sup>37</sup> Nonetheless, it was noted that many facilities find MACs difficult to administer and encounter difficulty sourcing GPs and other external service providers to serve on them.<sup>37</sup>

The evidence related to the effectiveness of medication review and associated QUM services on ensuring appropriate quality use of antipsychotics and benzodiazepines in the residential aged care setting is considered in Part 4 of the thesis.

## CHAPTER THREE: PSYCHOTROPIC MEDICATION USE IN RACFS

### 3.1 Psychotropic medication

A ‘psychotropic’ medication is defined as ‘*a chemical substance that acts primarily upon the central nervous system where it alters brain function, resulting in changes in perception, mood, consciousness and behaviour*’.<sup>56</sup> The main psychotropic drug classes are antidepressants, antipsychotics and anxiolytics/hypnotics.<sup>57</sup> All of these psychotropic drug classes are commonly prescribed for older people to manage mental health conditions.<sup>58,59</sup> In fact, studies have shown that older people are the largest per capita consumers of psychotropic medication.<sup>60</sup> In a large community sample in Sweden, for example, it was found that persons over the age of 84 used psychotropic medications at a significantly higher rate than people between the ages of 65 and 83 years (65% vs. 38%,  $p < 0.0001$ ).<sup>60</sup> Likewise, in a recent Australian study, use of anxiolytic and hypnotic drugs in the general population was considerably higher in those aged sixty-five and over, with peak use in those aged 85-89 years.<sup>61</sup>

Particular concerns have been raised with regard to the high rates of use of antipsychotics (also termed neuroleptics), anxiolytics and hypnotics (the latter two classes are predominantly benzodiazepines) in older people.<sup>14,62</sup> These three drug groups are separately classified as ‘psycholeptic’ drugs under the ‘NO5’ code in the World Health Organisation’s Anatomical Therapeutic Chemical (ATC) Classification System.<sup>57</sup> Table 3 lists the three psycholeptic drug groups, their ATC coding and provides key examples:

**Table 3: Psycholeptic drug groups<sup>57</sup>**

Psycholeptic drug group	ATC code	Key examples
Antipsychotics	N05A	Risperidone, haloperidol, olanzapine, chlorpromazine, quetiapine
Anxiolytics	N05B	Oxazepam, diazepam, alprazolam, lorazepam
Hypnotics/Sedatives	N05C	Temazepam, nitrazepam, zopiclone, zolpidem

### 3.2 Psychotropic medication and older people

It is well established that older people are vulnerable to drug-related problems.<sup>63-65</sup> As people age, their renal clearance declines, hepatic metabolism alters and blood flow to the liver is reduced; factors which affect the pharmacokinetics of many medications.<sup>64</sup> For instance, Tricyclic Antidepressants (TCAs), have a high ‘first-pass’ effect in the liver. As hepatic blood flow is reduced when people age, this results in higher plasma drug levels.<sup>66</sup> In addition to changes in drug metabolism, many older people suffer from multiple co-morbidities. As a consequence they are often prescribed multiple medications, meaning that the absorption,

metabolism and elimination of drugs may be altered further.<sup>64,65</sup> With ageing there is a decrease in lean body mass and total body water, and a relative increase in total body fat. This alteration leads to an increased volume of distribution for lipid-soluble drugs such as benzodiazepines, resulting in accumulation with continued use.<sup>66</sup> It is also hypothesized that older people have defects in the blood brain barrier which may permit increased access of psychotropic drugs into the Central Nervous System (CNS).<sup>67</sup>

Pharmacodynamics, a term which refers to the drug's physiologic effects, are also altered in older people.<sup>66</sup> Ageing is also associated with changes in the end-organ responsiveness to drugs at receptor or post-receptor level.<sup>66</sup> Sensitivity to benzodiazepines' central nervous system effects, for instance, increases as people age.<sup>66</sup> Thus, older people taking these medications experience sedation at lower doses and plasma concentrations than younger individuals.<sup>68</sup>

Certain medication adverse effects may also pose particular problems for older people. Anticholinergic adverse effects, including dry mouth, urinary hesitancy, confusion, and cardiac conduction abnormalities, may be exacerbated in people with co-existing cardiovascular disease, prostate disease or cognitive impairment; conditions that are much more prevalent in older people.<sup>64,69</sup> Psychotropic drugs are particularly likely to possess anticholinergic activity, which increases with dosages increase.<sup>70</sup> In a recent Australian study conducted in Sydney RACFs, over a third of the 602 residents were taking anticholinergic medications. The most common drug classes with anticholinergic activity taken by residents were psychotropic agents, specifically antidepressants (17%), and antipsychotics (10% of residents).<sup>71</sup>

### **3.3 Falls and psychotropic medication**

Falls in older people occur regularly, with more than 30% of older people (> over 65 years) estimated to fall at least once a year.<sup>72</sup> The impact of falls on public health is generally under-recognised. They are the primary reason for 85% of all injury-related admissions to hospitals and for more than 40% of RACF admissions.<sup>73</sup> In fact, falls and fall-related complications are ranked the fifth leading cause of death in the developed world.<sup>72</sup> One of the most severe outcomes of falling is a fracture, especially hip fracture. The one-year mortality rate after hip fracture is about 20%, with the majority of older people never returning to their pre-fracture levels of physical function and social activities.<sup>74</sup>

Multiple factors contribute to the risk for falls in older people but it is widely acknowledged that medications are an important contributor.<sup>73</sup> Two large meta-analyses, incorporating 62 studies conducted from 1966 to 2007, sought to quantify the effect of specific classes of drugs on the risk of falling in older people.<sup>73,75</sup> In addition, 'Bayesian pooled odds ratios' were calculated by combining data from both meta-analyses.<sup>73</sup> (Table 4)

**Table 4: Summary of the pooled odds ratios from Leipzig *et al.* and Woolcott *et al.* meta-analyses of the effects of drugs on risk of falling in older people**<sup>73,75,76</sup>

Drug Type	Leipzig et al Pooled odds ratio (95% CI)	Woolcott Pooled odds ratio (95% CI)	Woolcott Pooled Bayesian odds ratio (1966-2007) (95% CI)
Antihypertensives	Noninformative	1.26 (1.01-1.50)*	1.24 (1.01-1.50)*
Diuretics	1.08 (1.02-1.16)*	1.03 (0.84-1.26)	1.07 (1.01-1.14)*
Antipsychotics	1.50 (1.25-1.79)*	1.71 (1.44-1.50)*	1.59 (1.37-1.83)*
Antidepressants	1.66 (1.41-1.95)*	1.72 (1.40-2.11)*	1.68 (1.47-1.91)*
Benzodiazepines	1.48 (1.23 -1.77)*	1.60 (1.46-1.75)*	1.57 (1.43-1.72)*
Narcotics	0.97 (0.78-1.20)	0.89 (0.50-1.58)	0.96 (0.78-1.18)
NSAIDs	1.16 (0.97-1.38)	1.65 (0.98-2.77)	1.21 (1.01-1.44)*

\*Statistically significant odds ratio

The two meta-analyses found that psychotropic medication use in older people increased their risk of falls to a greater extent than all other medication classes.<sup>73,75</sup> The odds ratio for one or more falls with psychotropic drugs was 1.73 (95% CI 1.5-2.0), and there was little difference between the three main classes of psychotropic agents in regards to risk.<sup>73,75,77</sup> It is important to recognise, though, that all the studies included in the two meta-analyses were observational and there were no Randomised Controlled Trials (RCTs) included. One problem with observational studies is that confounding may influence outcomes. For instance, older people taking medications may be at higher risk of falling due to their underlying condition (e.g. insomnia, agitation) and this may result in an overestimation of risk due exclusively to a medication.<sup>78</sup> Another limitation to these meta-analyses is that the drug class classifications were extremely broad. For example, antidepressants such as TCAs, which are known to be strongly associated with a high risk of falls, were grouped with newer antidepressants which may have a lower rate of falls, potentially lowering the overall odds ratio.<sup>79</sup>

Another important risk factor for falls is multiple psychotropic medication use. Several studies have provided strong evidence of an increased falls risk when psychotropic agents are used concurrently.<sup>80-82</sup> In a RACF study of 177 residents, those residents taking two or more psychotropic agents were found to have a 3.2-fold increased risk of falling.<sup>82</sup> In Hanlon *et al.*'s U.S. longitudinal cohort study of over 3000 community-based older people, the risk of recurrent falls was 50% higher in those people taking a psychotropic agent or opioid analgesic. However, the risk was significantly higher (95%) when two or more of these agents were taken concurrently (Table 5).<sup>81</sup> This finding is concerning as many RACF residents take a combination of psychotropic drugs.<sup>60</sup> In two Australian studies approximately one third of RACF residents were taking at least two psychotropic medications.<sup>83,84</sup> Other factors associated with an increased falls risk in Hanlon *et al.*'s study included higher doses and extended duration of use of psychoactive agent.<sup>81</sup>

**Table 5: Multivariable relationship between CNS medication use and recurrent falls.<sup>81</sup>**

CNS medication use	Recurrent falls (2+ vs. 0-1) AOR (95% CI)	p value
Use of 2 or more agents	1.95(1.35-2.81)	< 0.0005
Use of one agent	1.55(1.22-1.97)	< 0.0005
No use	Reference	
High dose use (> 3SDD)*	2.89(1.96-4.25)	<0.0001
Moderate dose use (1-3 SDD)	1.80(1.31-2.47)	<0.0005
Low dose use (< 1 SDD)	1.42(0.95-2.15)	0.597
No use	Reference	
Long term use (< 2 years)	1.76(1.35-2.28)	<0.0001
Short term use	1.49(1.11-2.01)	<0.01
No use	Reference	

\*NB SDD is an abbreviation for Standard Daily Dose which is calculated by dividing the daily dose of a psychotropic agent by its minimal effective geriatric dose which is listed in the *Geriatric Dosage Handbook, 2007, 12Ed. Editors: Semla T, Beizer J & Higbee M.*

### 3.4 Psychotropic medication use in RACFs

Owing to increased susceptibility to adverse effects, dose accumulation with certain agents, multiple chronic disease, polypharmacy and increased falls risk, psychotropic medications should be used with considerable care in older people, and the use of two or more psychotropics, in particular, should be avoided.<sup>64</sup> However, the use of psychotropics in older people is high. Up to 39% of the older population in the community take at least one psychotropic agent, with significantly higher prevalence rates reported in RACF settings, ranging from 33% to 80% of residents.<sup>85-88</sup> There is also evidence that the use of psychotropic agents in RACF residents is increasing.<sup>88,89</sup> For example, when a Swedish research team compared RACF psychotropic use in 1982 with that recorded in 2000, large increases in both antidepressant (9% to 43%) and anxiolytic/hypnotic use (13% to 39%) were noted.<sup>88,90</sup> Likewise, significant increases have been found in RACF antipsychotic use in the U.S. and Canada over the past 10 years.<sup>91,92</sup>

Of the three key psychotropic classes, the most attention has been directed towards ensuring appropriate antipsychotic and benzodiazepine use as the prescribing of these particular psychotropic agents is widespread, there are doubts over their effectiveness and they are strongly associated with significant risks in older people.<sup>62,85,93</sup> There has also been considerable attention from both professional and regulatory authorities directed at rationalising the use of these medications.<sup>94-96</sup> Although antidepressants are also associated with risks, there is substantial evidence for their effectiveness in older people and they may actually be underutilised in the RACF setting.<sup>97,98</sup> For these reasons, this thesis is predominantly targeted at promoting guideline-based use of antipsychotics and benzodiazepines. The primary indications and adverse effects associated with these medications are outlined in the sections that follow.

### 3.5 Antipsychotics

Antipsychotic medications are commonly divided into two groups, the typical antipsychotics (also known as conventional antipsychotics) and the newer atypical antipsychotics (known as second-generational antipsychotics). These agents have been widely prescribed for the management of patients with schizophrenia, bipolar disorders, other psychotic disorders or conditions with severe behavioural disturbance.<sup>99</sup> The antipsychotic medications routinely used in Australia are listed in Table 6.<sup>100</sup> The most commonly used typical antipsychotics in Australia in 2002-2007 were haloperidol and chlorpromazine, whereas the most commonly prescribed atypical antipsychotics were risperidone, olanzapine and quetiapine.<sup>101</sup> In 2007, 70% of the antipsychotics prescribed for Australians over 60 years of age were for atypical agents.<sup>101</sup>

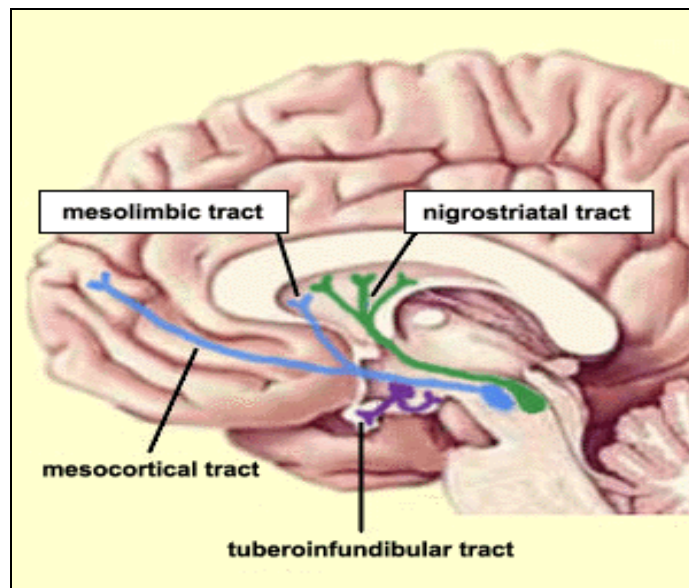
**Table 6: Antipsychotic medications used in Australia and Pharmaceutical Benefits Scheme (PBS) listing details<sup>102</sup>**

	Generic name	Trade name
<b>Typical antipsychotics:</b>	chlorpromazine*	Largactil
	trifluoperazine*	Stelazine
	haloperidol*	Serenace
<b>Atypical antipsychotics:</b>	clozapine†	Clozaril
	risperidoneβ	Risperdal
	olanzapine¥	Zyprexa
	quetiapine	Seroquel
	aripiprazole	Abilify
* Indicated for short term management of anxiety, agitation or disturbed behaviour in non-psychotic disorders.		
† Available under the S100 scheme restricted authority.		
β PBS authority listing for behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful.		
¥ Indicated for use for behavioural and psychological symptoms in dementia (Intramuscular (IM) only). PBS authority listing for treatment of schizophrenia.		

Antipsychotic drugs have a variety of pharmacological actions but they all competitively block dopamine D2 receptors throughout the CNS, although their affinity for the receptors varies.<sup>103</sup> Their effect on psychotic symptoms is attributed to blockade of D2 receptors in the cerebral mesolimbic tract; however, the blockade of dopamine D2 receptors in other cerebral pathways (the mesocortical and nigrostriatal tracts as shown in Figure 3) can result in severe involuntary movement disorders, known as Extra Pyramidal Symptoms (EPS).<sup>14,104,105</sup>

Aside from their effect on D2 receptors, antipsychotics can also antagonise muscarinic, histaminergic, serotonergic and alpha-adrenergic receptors, again to varying extents.<sup>103</sup> This variability, along with D2 receptor affinity, accounts for the wide range of adverse effects seen with different antipsychotics.<sup>103</sup>

**Figure 3: Anatomy of dopamine tracts in the brain<sup>106</sup>**



In general, the higher a drug's affinity for a receptor, the more prominent the intended effect or adverse effect will be. High D2 receptor-affinity antipsychotic medications, such as haloperidol, have a higher incidence of movement disorders. The low D2 receptor-affinity antipsychotics, including chlorpromazine and the newer atypical antipsychotics, have a lower incidence of movement disorders.<sup>14</sup> Lower D2 receptor-affinity antipsychotics may be associated with a higher incidence of other adverse effects such as sedation, postural hypotension and anticholinergic side effects depending on their receptor binding affinities which are listed in Table 7 below.<sup>14,103</sup>

**Table 7: Relative receptor binding affinities of the common antipsychotics<sup>103</sup>**

Antipsychotic	Receptor:				
	D <sub>2</sub>	M <sub>1</sub> (ACh)	5HT <sub>2</sub>	H <sub>1</sub>	α <sub>1</sub>
Haloperidol	++++	-	+	-	+
Chlorpromazine	+++	++	++	++	+++
Risperidone	+++	-	++++	+++	+++
Olanzapine	++	++	++++	+++	+
Quetiapine	++	+	++	++	++
Clozapine	+++	++++	++++	++++	++++

++++ = very high affinity; +++ = high affinity; ++ = moderate affinity; + = weak affinity - = no affinity

( D = dopaminergic; M = muscarinic; 5HT = serotonergic; H = histaminergic; α = adrenergic)

### 3.5.1 Antipsychotics and movement disorders

One of the movement disorders associated with antipsychotic use is 'akathisia', which is defined as motor restlessness in which the patient is compelled to keep moving.<sup>14,104</sup> Another



commonly seen EPS is parkinsonism which presents with shuffling gait, tremor and rigidity.<sup>14,107</sup> A more serious antipsychotic-induced EPS, 'tardive dyskinesia', is a potentially irreversible movement disorder causing abnormal involuntary movements, mostly involving the tongue, mouth and face, that occurs months to years after antipsychotic exposure.<sup>14,105,108</sup> The risk factors for the development of tardive dyskinesia include duration of antipsychotic treatment, increasing age, and dementia.<sup>15</sup>

Atypical antipsychotics such as risperidone, olanzapine and quetiapine became available in the early 2000s.<sup>109</sup> The reason they are termed 'atypical' is due to the perception that these medications share a lower risk of EPS than older typical antipsychotics.<sup>100</sup> As a consequence they are increasingly prescribed in preference to them.<sup>90,110-113</sup> Like typical antipsychotics, the newer atypical antipsychotics block D2 receptors; however, they also block 5-HT<sub>2</sub> receptors, an attribute thought to decrease EPS risk.<sup>100</sup> Further, they are theorised to dissociate faster from the D2 receptor and possess less extrastriatal D2 occupancy.<sup>114</sup> It is important, nonetheless, to recognise that the receptor binding profile of each antipsychotic, whether atypical or typical, differs.<sup>115</sup> For instance, risperidone has a higher affinity for the D2 receptor than quetiapine, meaning lower doses are required for effect; however, it has a higher EPS risk.<sup>116</sup> The EPS risk appears to be dose-related, with higher rates of EPS recorded with increasing dosage.<sup>115</sup>

With regards to EPS rates, several meta-analyses have documented an advantage for atypical antipsychotics over typical agents.<sup>116</sup> However, there is a scarcity of head-to-head studies and when comparisons are made, high dose haloperidol, the highest potency typical antipsychotic, is usually the comparative drug, potentially overstating the advantage of the atypical class.<sup>104,115</sup> Most studies are also conducted in patients diagnosed with schizophrenia rather than dementia, where higher doses of antipsychotics are used and the sample is much younger.<sup>116,117</sup> Two recent large Canadian retrospective cohort studies have provided data that the EPS risk, both acute and long term, does not appear to differ significantly between atypical and typical agents, when used in older people.<sup>108,113</sup> Further research is required to clearly define the EPS risk variance between atypical and typical agents in this population.

### **3.5.2 Other adverse effects associated with antipsychotic use**

Antipsychotics, both typical and atypical, are associated with a wide range of adverse effects. Receptor binding characteristics of individual antipsychotics largely determine the adverse effects experienced by patients (see Table 7). The more sedating agents tend to have a low incidence of EPS but a higher incidence of postural hypotension and anticholinergic side effects. Conversely, relatively non-sedating agents tend to have a high incidence of EPS but a low incidence of postural hypotension and anticholinergic side effects.<sup>118</sup> Table 8 links the receptor affinity of antipsychotics to their most likely adverse effects.<sup>103</sup>

**Table 8: Adverse effects of antipsychotics<sup>103</sup>**

<b>Receptor affinity</b>	<b>Adverse effects</b>
Dopaminergic (esp D2)	EPS (i.e. parkinsonism, akathisia, tardive dyskinesia) galactorrhoea, gynaecomastia, pigmentation
Muscarinic (anticholinergic)	dry mouth, reduced sweating, blurred vision, raised intraocular pressure, urinary retention, constipation, impotence, tachycardia, confusion, memory impairment, delirium, cardiotoxicity.
Adrenergic ( $\alpha$ )	postural hypotension, tachycardia, arrhythmia, insomnia, tremor
Serotonergic	weight gain, sedation
Histaminic	sedation, hypotension, weight gain
Miscellaneous	photosensitivity and pigmentation (esp. phenothiazines) reduced seizure threshold (mainly typical agents)

Lower D2-affinity typical antipsychotics such as chlorpromazine are more sedating than haloperidol.<sup>103</sup> Among the atypical antipsychotics, olanzapine and quetiapine are more sedating than risperidone.<sup>118</sup> Sedation tends to be most pronounced at initiation of therapy or dose increase, although the degree of sedation tends to decline over 1-2 weeks.<sup>119</sup>

Every antipsychotic agent possesses some degree of anticholinergic activity with the exception of both low-dose risperidone and haloperidol.<sup>119</sup> Choosing antipsychotic medications with less anticholinergic properties is an important consideration in older people, who are not only susceptible to these adverse effects but polypharmacy often occurs in an attempt to treat them. For example, the anticholinergic effect of constipation leads to increased use of laxatives.<sup>118</sup> Central anticholinergic effects range from sedation and confusion to delirium, agitation and severe cognitive decline.<sup>120</sup> A meta-analysis examining the adverse effects of atypical antipsychotics in older people with dementia concluded that the newer agents had the same detrimental effect on cognition as older typical antipsychotics.<sup>112</sup>

Antipsychotics that have some degree of alpha-adrenergic blocking activity will increase the risk of postural hypotension, a phenomenon associated with a higher falls risk in older people. All antipsychotics can cause postural hypotension although the incidence is higher with chlorpromazine and risperidone.<sup>119</sup> In a prospective cohort study of 2005 Sydney RACF residents, olanzapine was associated with a higher risk of falling than risperidone or typical antipsychotics.<sup>121</sup>

The elevation of prolactin level is more likely to occur with antipsychotics that possess high affinity for the D2 receptor, particularly risperidone and haloperidol.<sup>119,120</sup> The elevation is dose- dependent and will manifest as galactorrhea and gynaecomastia.<sup>120</sup> Prolactin elevation has

also been associated with a decrease in bone density and osteoporosis, which may be problematic for older frail women who are already at increased risk of falls and fractures.<sup>118</sup>

Although hyperglycaemia has been reported with typical antipsychotics, the magnitude of effect is greater with the atypical antipsychotics.<sup>122</sup> Olanzapine, in particular, is associated with abnormal glucose tolerance, weight gain and increased serum lipids, placing patients at increased risk for diabetes and cardiovascular disease.<sup>118</sup> Diabetic patients taking atypical antipsychotics should be monitored closely for worsening of glycaemic control and those patients considered at risk of developing diabetes should have routine fasting blood glucose measurements.<sup>123</sup>

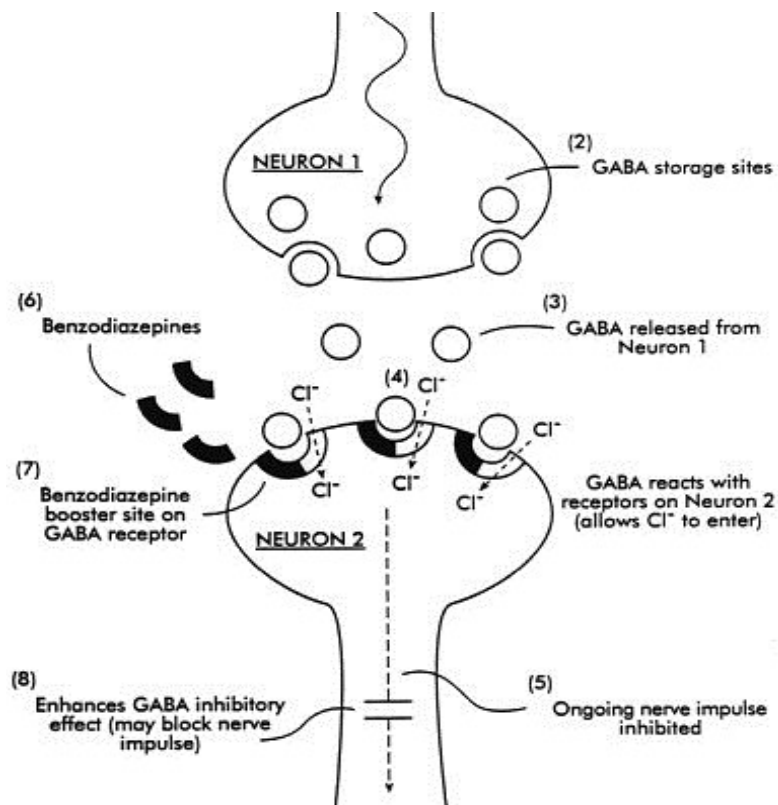
Finally, a rare, but clinically significant, adverse effect associated with antipsychotics is sudden cardiac death, with torsades de pointes and other severe cardiac arrhythmias theorised to be the main causes.<sup>124</sup> A prolonged QT interval predisposes to arrhythmias, especially in older people.<sup>125</sup> It is well known that typical antipsychotics prolong the QT interval; however, atypical antipsychotics have also been shown to have this effect, especially ziprazidone and quetiapine.<sup>124</sup> Several trials have shown that older people taking either typical or atypical antipsychotics have approximately a two-fold increase in the risk of sudden cardiac death, with the incidence increasing with higher dose, age and co-morbid cardiac disease.<sup>126-128</sup> For this reason an electrocardiogram (ECG) is recommended for all older people before antipsychotic treatment is initiated, with periodic ECG monitoring when higher doses are prescribed or in patients with cardiac disease.<sup>125</sup>

### **3.6 Benzodiazepines**

Benzodiazepines exert their effect by binding to a specific site on Gamma-aminobutyric acid type A (GABA<sub>A</sub>) receptors which are chloride-selective ion channels that are physiologically activated by GABA, the major inhibitory neurotransmitter in the brain.<sup>129</sup> When benzodiazepines bind to these receptors they increase the effect of GABA via enhancement of chloride release into neurons (see Figure 4).<sup>130,131</sup>

Benzodiazepines have many properties including anxiolytic, anti-convulsive, muscle-relaxant and hypnotic actions.<sup>130</sup> They were introduced into practice in the 1950s and quickly became widely used for a variety of psychiatric indications, principally anxiety and insomnia.<sup>132</sup> These drugs are also used as augmentation therapy in bipolar disorder and schizophrenia, and to manage behavioural and psychological symptoms.<sup>133</sup>

**Figure 4: Action of benzodiazepines at a synapse<sup>131</sup>**



### **3.6.1 Pharmacokinetics and pharmacodynamics of benzodiazepine use in older people**

As people age they become more sensitive to the effects of benzodiazepines. The pharmacodynamic alterations associated with the ageing brain may be more important in explaining the increased sensitivity of older people to benzodiazepines than pharmacokinetic changes. Researchers have suggested that GABA receptors become more responsive with age and that the inhibitory effects resulting from benzodiazepines may be expressed to a greater degree in people with dementia.<sup>133</sup>

There are marked changes in the pharmacokinetics of benzodiazepines in older people, impacting on plasma levels and drug distribution:

- Serum albumin levels decrease by up to 20%, potentially leading to an increase in the free benzodiazepine fraction in plasma and increased effects.
- Age-related reduction of hepatic blood flow reduces metabolism, increasing plasma concentrations.
- There is an increased volume of distribution of benzodiazepines caused by increased proportion of total body fat to lean body mass, thus prolonging half-life.<sup>133</sup>

Benzodiazepines can be divided into three main groups, long-, intermediate-, and short-acting, based on their elimination half-life. Table 9 overleaf lists the benzodiazepines available in Australia. Unlike short and intermediate agents, long-acting benzodiazepines undergo hepatic oxidative metabolism making them sensitive to age-related alterations in hepatic function. When the kinetics of diazepam and oxazepam in older people were directly compared, absorption of diazepam was found to be faster but its overall elimination was slower. Although there was little difference between oxazepam and diazepam in effect, sedative effects persisted for 2 weeks after diazepam was ceased.<sup>134</sup> In older adults, short to intermediate-acting benzodiazepines, metabolised by glucuronidation as opposed to oxidation, are generally preferred because there is less risk of accumulation and resultant sedation and confusion.<sup>135</sup> Alprazolam, a highly potent, short-acting agent may lead to rebound symptoms and is not recommended for older people.<sup>136</sup>

**Table 9: Benzodiazepines commonly available in Australia<sup>137</sup>**

	Generic name	Trade Name
<b>Long acting</b> (half-life >24hr)	diazepam	Valium Ducene Antenex Valpam
	nitrazepam	Mogadon Alodorm
	lorazepam	Ativan
<b>Intermediate Acting</b> (12-24hrs)		
<b>Short acting:</b> (6-12hrs)	alprazolam	Xanax Kalma Alprax
	oxazepam	Serepax Murelax Alepan
	temazepam	Temtabs Temaze Normison

### 3.6.2 Adverse effects of benzodiazepines

There are numerous risks associated with benzodiazepine use which are amplified in older people.<sup>138</sup> Many of the adverse effects are dose-dependent and there is evidence that some, such as cognitive impairment, increase with duration of benzodiazepine use.<sup>133</sup> Due to the lack of clinical trials evaluating the long-term use of these agents there is uncertainty over whether adverse effects diminish over time, in a similar fashion to benzodiazepines' therapeutic effects. Cognitive impairment has long been associated with benzodiazepine use in older people.<sup>133</sup>

Pomera *et al.* compared the effect of diazepam in older and younger patients, concluding that older people were more sensitive to the development of cognitive impairment.<sup>139</sup> The main impairments occur in memory and information processing, although several studies have reported negative impacts across the board on all cognitive performance scores.<sup>140,141</sup> Anterograde amnesia, an inability to recall new information, is one of the main effects, occurring with all benzodiazepines.<sup>142</sup> The severity of memory impairment appears to vary with the dose and type of benzodiazepine used, although older people can experience amnesic effects at very low doses.<sup>142</sup> There is some uncertainty concerning the impact of benzodiazepine use on cognition over prolonged periods, with some researchers finding no effect and others reporting worsened cognitive performance.<sup>141</sup> In a nine year follow-up study of 2 105 older people, higher doses and cumulative exposure to benzodiazepines correlated with worsened cognitive impairment over time, even though the researchers noted that the effect size was small.<sup>141</sup> Taking benzodiazepines for prolonged periods may have effects which may persist after medication is ceased. A review of ten studies reported that even though cognitive performance improved after benzodiazepine withdrawal, significant impairment in cognition continued to be evidenced 6 months later when compared to controls.<sup>143</sup>

Benzodiazepine use can also contribute to psychomotor impairment whereby reaction time is slowed and tasks requiring attention and concentration are markedly disrupted.<sup>144,145</sup> Other psychomotor effects include impaired vision, unsteady gait, reduced visuospatial ability, and impaired motor-coordination.<sup>142</sup> Generally, psychomotor impairment appears to be strongly dose-related and is worse following initial exposure or with a dosage increase.<sup>142,144,145</sup>

Another adverse effect associated with benzodiazepine use involves a phenomenon known as ‘paradoxical disinhibition’ whereby the patient may become more anxious, excited, hostile, aggressive and impulsive.<sup>145</sup> Paradoxical effects, although uncommon, occur at a greater rate in older people and, in rare cases, can result in violence to other people and damage to property.<sup>144,145</sup> These reactions are thought to be due to benzodiazepines’ inhibition of social control mechanisms.<sup>138</sup>

### **3.6.3 Benzodiazepines and falls risk**

One of the main concerns with benzodiazepines is that for more than two decades, use has been recognised as an independent risk factor for falls and hip fractures in older people.<sup>73,75,146,147</sup> A 2003 review of studies assessing the association between the use of benzodiazepines and hip fracture risk concluded that the use of these drugs by older people increased their risk of hip fracture by over 50%.<sup>148</sup> The risk is similar in the RACF setting. Ray *et al.* specifically examined the risk of falls in 2 510 residents taking benzodiazepines in 53 U.S. RACFs. After adjusting for various confounders including disability, cognition, past falls and other medication, residents taking benzodiazepines had a 44% higher rate of falls than non-users.<sup>149</sup>

There is conflicting evidence over whether long-acting benzodiazepines are associated with a greater risk of falling than short-acting benzodiazepines. Ray *et al.* reported a 73% increased risk of falling in residents taking a long half-life benzodiazepine compared to a 15% and 45% increased falls risk in residents taking short and intermediate half-life benzodiazepines, respectively.<sup>149</sup> However, in direct contrast, a more recent study of hospital inpatients found that lorazepam and alprazolam were associated with a significantly higher fall rate than diazepam.<sup>150</sup>

In terms of falls risk, it appears that the daily dose and duration of use of benzodiazepines are more important than the specific half-life of the agent used.<sup>76,147,148</sup> In a nested case-control study within the large Rotterdam study, a population-based cohort study in 7983 older people, a significantly higher risk of fracture was found in 'high-dose' users (> 10mg of diazepam equivalents/day) irrespective of benzodiazepine type.<sup>147</sup> In Ray *et al.*'s RACF study, the risk of falling doubled as diazepam equivalent doses increased from 2mg or less/day (adjusted odds ratio: Adjusted Odds Ratio (AOR) 1.30 (95% CI: 1.12-1.52) to 8mg/day or greater (AOR 2.21 (95% CI: 1.89-2.60)).<sup>149</sup>

Although the risk of falling in Ray *et al.*'s study was found to be at its highest the first week after initiation, the risk still remained elevated after 30 days.<sup>149</sup> In a recent U.S. case-control study, analysing data from older patients, the highest hip fracture risk was found in new benzodiazepine users who had started treatment within 14 days (AOR 2.05 (95% CI: 1.52-2.77), compared to the risk associated with users taking a benzodiazepine for longer than 90 days (AOR 1.58 (95% CI:1.31-1.89)).<sup>151</sup> In the Rotterdam study, the highest risk of fracture was associated with a longer duration of use (14-90 days), however, the risk declined after 90 days.<sup>147</sup> The exact mechanism how benzodiazepines increase the risk of falling has not been defined, however studies have shown that benzodiazepines affect neuromuscular processing to a greater extent in older people resulting in increased postural sway and loss of balance.<sup>68,152</sup> The effects on gait and balance are most marked after initial administration.<sup>153</sup> Long term users may develop a degree of tolerance to these effects which may help explain the observation that the risk of falling is greatest in the first few weeks following initiation and then declines.<sup>148</sup>

#### **3.6.4 Dependence and tolerance to benzodiazepines**

The present criteria for substance dependence includes tolerance, escalation of dosage, continued use despite efforts to stop, preoccupation with acquisition, and a withdrawal syndrome.<sup>4</sup> Benzodiazepines meet all these criteria. There is a general consensus among some researchers that the risk of benzodiazepine dependence increases with higher doses, short-acting high potency agents, longer duration of treatment and individual patient factors, including co-morbid medical conditions, for instance, depression and chronic pain.<sup>133,154</sup> The risk of dependence increases with age and is more common in chronically ill older patients using multiple medications.<sup>133</sup>

Following initial administration of a benzodiazepine, a person can feel sleepy and uncoordinated, but tolerance to these sedative effects develops rapidly. After a few weeks physical dependence takes place, which presents as a withdrawal syndrome when the benzodiazepine is reduced or abruptly stopped.<sup>129</sup> Physical dependence is characterised by rebound and withdrawal symptoms.<sup>133</sup> Rebound symptoms are basically an intensified return of the symptoms for which the benzodiazepine was originally prescribed for. It is the most common consequence of prolonged benzodiazepine use and may last a few days to weeks after discontinuation.<sup>133</sup> Rebound symptoms can be minimised by gradual tapering of dosage.<sup>144</sup> Withdrawal reactions are likely to occur after abrupt cessation of benzodiazepines and symptoms include agitation, dysphoria, perceptual disturbance, confusion, delirium and seizures (Table 10).<sup>115</sup> The reported incidence of the withdrawal syndrome varies between 30%-100%, however it is difficult to gauge the exact incidence as about half of long-term benzodiazepine users drop out of withdrawal studies.<sup>154,155</sup> Some elements of withdrawal are believed to occur in most patients who have taken therapeutic dosages for more than a few months.<sup>145</sup> Symptoms come on within 48 hours of stopping a medium-acting benzodiazepine, and 5-10 days of stopping long-acting agents such as diazepam.<sup>144</sup>

**Table 10: Symptoms of benzodiazepine withdrawal<sup>154</sup>**

<b>Common Symptoms</b>	<b>Less common symptoms</b>
Anxiety, panic attacks, agoraphobia	Perceptual distortions, sense of movement
Insomnia, nightmares	Depersonalisation
Depression, dysphoria	Hallucinations
Excitability, restlessness	Distortion of body image
Poor memory and concentration	Tingling, numbness
Dizziness	Formication (skin crawling)
Weakness	Sensory hypersensitivity (light, sound, taste, smell)
Tremor	Muscle twitches, jerks, tinnitus
Muscle pain	
Sweating	
Palpitations	
Blurred or double vision	

Symptoms of withdrawal in older people may be different to those experienced by younger people.<sup>133</sup> In a prospective study of benzodiazepine withdrawal in older inpatients, confusion was the predominant withdrawal effect after benzodiazepines had been discontinued abruptly.<sup>156</sup> Rebound anxiety and insomnia symptoms were not commonly experienced. The authors speculated that the slower clearance of benzodiazepine medication in older people may modulate the symptoms of withdrawal.<sup>156</sup>

Chronic benzodiazepine use can result in tolerance and develops at different rates and to different degrees for the various effects.<sup>145,157</sup> Tolerance develops rapidly to sedative and motor-coordination deficits; whereas tolerance appears to develop more slowly to the anxiolytic or memory impairing effects of benzodiazepines.<sup>157</sup>



There is some debate between experts in the field regarding whether benzodiazepines cause dependence or not. Some clinicians argue that the majority of users do not increase their dosage and that patients report effectiveness even after several years of use.<sup>158</sup> The situation is not clear cut because there is a lack of long term RCTs lasting for longer than two to four weeks. Likewise, there are few studies of high quality that investigate whether benzodiazepines continue to have effectiveness on anxiety and sleep measures after periods exceeding 4 weeks.

One Canadian study assessed quality of sleep and benzodiazepine use using the cross-sectional 'Quebec Survey on Senior's Health', completed in 2005-2006 by 2 798 subjects, all of whom were 65 years or older.<sup>159</sup> It was found that benzodiazepine users reported poorer quality of sleep than non-users, and that their daytime functioning was consequently impaired.<sup>159</sup> A limitation of this study was that the duration of and quantity of benzodiazepine use was not documented. In spite of this, the authors concluded that the reason why benzodiazepines did not improve the quality of sleep over the long term was because they had become ineffective as a result of the physiological tolerance mechanism; however, they stressed that high quality prospective longitudinal studies were needed to confirm this finding.<sup>159</sup>

The pharmacological mechanisms underlying benzodiazepine tolerance and withdrawal are complex and ill defined.<sup>154,157</sup> It is theorised that chronic exposure to benzodiazepines reduces the function of the GABA receptor, which then requires more agonist to achieve the desired result.<sup>157</sup> Rapid withdrawal of benzodiazepines once tolerance has developed exposes the patient to underactivity of inhibitory GABA functions, with a resultant surge of excitatory nervous activity. The receptor changes may be slow to reverse and may do so at different rates, possibly explaining the variable time of emergence and duration of individual withdrawal symptoms.<sup>154</sup>

The largest group of benzodiazepine dependent patients are older long-term users who have inadvertently become dependent as a result of regular repeat prescriptions over months to years.<sup>154</sup> The size of this group is thought to approach one million in the U.K., four million in the U.S. and include many millions of patients worldwide.<sup>154</sup> Although trials have shown that older patients can withdraw successfully from treatment it is clearly better to prevent dependence from developing in the first place by prescribing benzodiazepines only when appropriate, at the lowest effective dose and for short periods of time.<sup>154</sup>

### **3.7 Antipsychotic and benzodiazepine use and old age mental health conditions**

Antipsychotic medications are primarily indicated for people with schizophrenia, bipolar disorders and other psychotic behaviour disorders.<sup>99</sup> In older people, however, it is well established that the most common indication for these medications is to treat behavioural disturbances associated with dementia.<sup>101,160</sup> Similarly, although benzodiazepines are indicated for the short-term treatment of anxiety and sleep disorders, it has been suggested that they are

often prescribed to older people for nonspecific physical, behavioural and psychological symptoms.<sup>133,161</sup> In order to appreciate why these agents are used so extensively in older people, especially in the RACF setting, it is important to outline the common old age mental health conditions of dementia, anxiety and sleep disturbance, consider the evidence regarding the benefits and risks associated with the use of psychotropic medication for these indications and finally, to briefly discuss and review relevant clinical guidelines relating to their use.

Greater emphasis has been placed on describing the disorders and their evidence-based treatment rather than an in-depth analysis of the guidelines themselves. Although there are several Australian clinical guidelines on psychotropic use which, on the whole, align closely with the research evidence, qualitative research conducted in Part three of this thesis revealed that clinical guidelines were rarely adopted by health professionals working within Tasmanian RACFs. Thus, a detailed critical review of the currently available guidelines was not considered pertinent to this body of research.

## CHAPTER FOUR: MANAGEMENT OF DEMENTIA

### 4.1 Dementia overview

The WHO International Classification of Diseases (ICD-10) defines dementia as:

*‘A syndrome due to a disease of the brain, usually of a chronic or progressive nature, in which there is a disturbance of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, language and judgment. Consciousness is not clouded. The impairments of cognitive function are commonly accompanied by deterioration in emotional control, social behaviour, or motivation.’<sup>162</sup>*

Put simply, dementia expresses itself in three areas; cognitive impairment, behavioural symptoms and difficulties carrying out daily functions.<sup>163</sup> The prevalence of dementia increases with age, from about 3% at 70-74 years, to 20% at 85-89 years, and 40% at 95 years or over.<sup>164</sup> People with dementia become increasingly dependent on informal carers and formal care services as their condition progresses.<sup>165</sup> They are also at high risk of developing delirium, depression and sleep disturbance.<sup>165</sup> In Australia, many people with dementia will enter RACFs when they require support to perform Activities of Daily Living (ADLs), or due to challenging behavioural and psychological symptoms.<sup>164</sup>

#### 4.1.1 Types of dementia

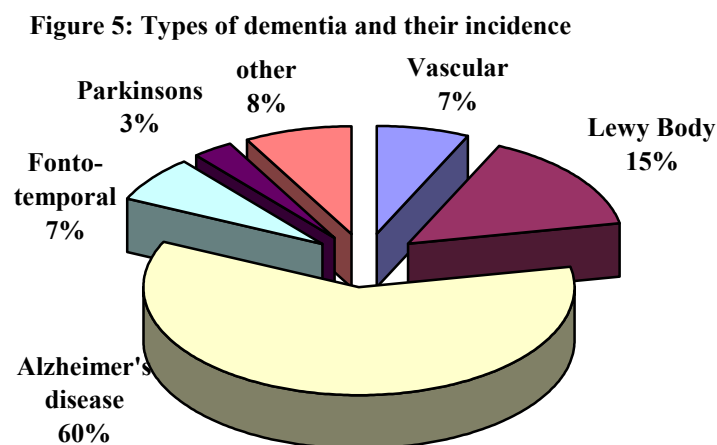
Although there are many different types of dementia, four main sub-types predominate but more often cases of ‘mixed dementia’ predominate where features of two or more types of dementia co-exist. The four main dementia types are:

- a. Alzheimer’s Disease: The most common type of dementia is caused by Alzheimer’s disease, accounting for 50-70% of all cases of dementia.<sup>119</sup> Age is a strong risk factor, with the disease affecting 8% of people over 65 years, increasing to 30% over 85 years.<sup>166</sup> There are characteristic changes in the brains of patients with Alzheimer’s disease caused by the aggregation of neurotoxic beta-amyloid and tau proteins.<sup>119</sup> As the disease progresses, extra-cellular plaques and intra-cellular tangles form in specific regions of the brain such as the hippocampus (responsible for memory and storage) ultimately resulting in the destruction of cholinergic and other neurons.<sup>119</sup> Alzheimer’s disease is characterised by a gradual onset of symptoms, with initial forgetfulness which progresses to profound memory impairment.<sup>14</sup> There is also a progressive deterioration in the ability to perform ADLs and behavioural change.<sup>164</sup>
- b. Dementia with Lewy bodies: Dementia with Lewy bodies accounts for up to 15 of dementias.<sup>167</sup> Lewy bodies are spherical bodies that are found in the cerebral cortex of patients

with this type of dementia.<sup>168</sup> The principal hypothesis for Lewy body formation involves the abnormal aggregation of alpha-synuclein protein. As the disease progresses, normal axonal transport is blocked leading to full neuronal degeneration.<sup>168</sup> Patients with dementia with Lewy bodies demonstrate pathological changes that overlap with Parkinson's disease. Indeed, Lewy bodies are also found in the brains of patients with Parkinson's disease but in the midbrain, rather than in the cerebral cortex.<sup>168</sup> The progression of dementia with Lewy bodies is more rapid than Alzheimer's disease, with severe dementia and signs of Parkinsonism, including rigidity, occurring within 1-2 years. The characteristic features of dementia with Lewy bodies are fluctuations of awareness and visual hallucinations that occur frequently.<sup>168</sup>

c. Vascular dementia: Since 1985, multi-infarct dementia has been termed 'vascular dementia', with the exact prevalence debated.<sup>14</sup> Pure vascular dementia without Alzheimer's disease appears to be uncommon.<sup>14,167</sup> Individuals with this type of dementia usually have vascular risk factors; specifically, hypertension, diabetes, arterial disease and/or smoking.<sup>169</sup> The role of vascular disease in the aetiology of vascular dementia is not fully elucidated.<sup>169</sup> Most patients present with signs of stroke or other vascular problems such as ischaemic heart disease. Accordingly, imaging evidence of cerebrovascular disease in the frontal lobe is commonly seen.<sup>170</sup> The onset of vascular dementia may be abrupt or there may be periods of decline followed by relative stability.<sup>170</sup> Physical problems such as urinary incontinence, gait disturbance are more pronounced in vascular dementia than in Alzheimer's disease.<sup>170</sup>

d. Fronto-temporal dementia: Although fronto-temporal dementia accounts for less than 10% of dementia patients, it represents the second highest cause of dementia in patients younger than 65 years of age, after Alzheimer's disease.<sup>119</sup> Pathologically, cortical atrophy is a major finding in patients with the disease and a family history of the disease is not uncommon. Initially, social disinhibition and lack of insight are more common than memory problems. Disturbance of mood and speech are frequent.<sup>119</sup> Figure 5 illustrates the prevalence of each dementia type.



### **4.1.2 Diagnosis of dementia**

Accurately diagnosing dementia is important for several reasons. Firstly, other causes/contributors of memory loss can be excluded or addressed. Second, an early diagnosis allows adjustment and planning by families. Finally, early diagnosis will allow the opportunity to initiate early symptomatic treatment.<sup>171</sup> The diagnosis of dementia is made clinically on the basis of the history, neuropsychological assessment, investigations and physical examination.<sup>14</sup>

The most commonly used diagnostic classification scale for mental disorders is the Diagnostic and Statistical Manual of the American Psychiatric Association – Text Revision (DSM-IV-TR) (Table 11).<sup>4</sup> In order for a diagnosis to be made, the cognitive deficits must be severe enough to cause impairment in occupation or social functioning and must represent a decline from a previous level of functioning.<sup>14,64</sup>

**Table 11: Diagnostic criteria for dementia<sup>4,14</sup>**

A	1. Memory impairment, AND
	2. At least one of the following:
	a) disorder of language (aphasia)
	b) inability to carry out motor activities (apraxia)
	c) inability to recognise objects (agnosia)
	d) impairment of abstract thinking, judgement, planning (executive functioning)
B.	The disturbance in A1 and A2 significantly interferes with work or usual social activities or relationships with others.
C.	Course is marked by gradual onset and continuing decline.

Obtaining a detailed history is an essential part of the assessment of a patient with suspected dementia.<sup>164,171</sup> In addition, a physical examination should determine if any general medical condition (e.g. thyroid disease, hydrocephalus, brain lesion or a stroke) might be causing or exacerbating the dementia.<sup>64,171</sup> The examination should also include an assessment of functional abilities and neurological testing.<sup>64</sup>

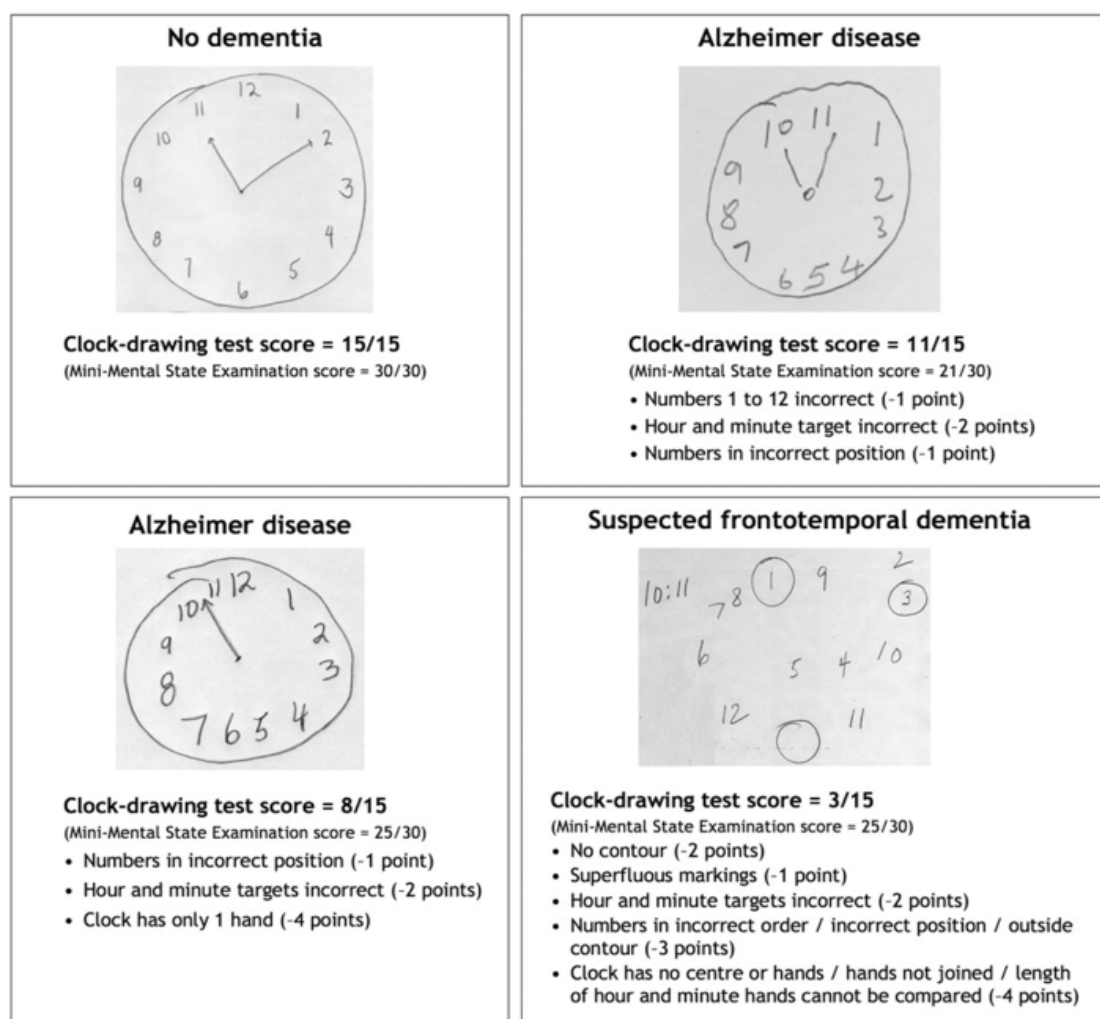
### **4.1.3 Cognitive testing**

All people evaluated for dementia should have their cognitive function evaluated.<sup>171</sup> The aim of cognitive testing is to ascertain the severity and characteristics of impairment and to measure changes in function over time.<sup>172</sup> These tests assist in the differentiation between the types of dementia and can also rule out differential diagnoses such as depression.<sup>172</sup> The Mini-Mental State Examination (MMSE) is the most widely utilised neuropsychological tool to assess for cognitive impairment (Appendix B).<sup>164</sup> This test provides a superficial assessment of memory, language and visuoperceptual function.<sup>173</sup> The MMSE requires little training, is quick to administer and is widely accepted.<sup>165</sup> Patients with Alzheimer's disease are likely to score at

least 18-26 out of 30 on the MMSE in mild disease, 10-18 for moderate disease and 9 or less for severe disease.<sup>173</sup> Although used extensively in practice and in research, the MMSE has its limitations. For instance, it lacks sensitivity at higher scores for a diagnosis of mild dementia.<sup>171</sup> Language barriers and low education can also provide false-positive scores.<sup>171</sup> The clock drawing test is also used widely for dementia screening and evaluates executive functioning as well as visuospatial abilities (Figure 6).

**Figure 6: Clock drawings and test scores for patients with and without dementia<sup>171</sup>**

(Participants are asked to draw a clock face with all the numbers on it, and to show the time as 10 minutes past 11).



Like the MMSE, the clock drawing test may lack sensitivity for the diagnosis of mild dementia.<sup>171</sup> To differentiate between mild dementia and age-related memory impairment more detailed neuropsychological tests are often performed such as the Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog).<sup>172</sup> These tests are of a longer duration, are more sensitive than the MMSE and also assess reasoning and comprehension skills.<sup>171</sup> Limitations to

the use of these tests are that they are expensive and take several hours to complete, which often precludes their use in clinical practice.<sup>171</sup> The ADAS-Cog is predominantly used by researchers in clinical trials as a means of evaluating if various treatments result in improvements in cognition and/or functioning.

#### **4.1.4. Dementia, delirium or depression?**

In some people, depression or delirium can be misdiagnosed as dementia. The relationship between these three conditions is complex as dementia patients are at increased risk of depression and delirium, and the conditions often co-exist.<sup>174</sup> It is also thought that depression and delirium are independent risk factors for the development of dementia.<sup>174,175</sup>

Delirium is a medical emergency presenting with acute confusion, impaired attention and fluctuations in levels of consciousness.<sup>171</sup> These symptoms can develop over hours to days and the duration of illness varies from hours to weeks, whereas the deficits of dementia tend to be stable or progressive, and level of consciousness is unaffected.<sup>64,119</sup> Delirium can be due to a number of causes which are usually multi-factorial and reversible.<sup>164</sup> The most common causes are infections (usually urinary tract and lung), toxicity to drugs (especially anticholinergics) or drug or alcohol withdrawal.<sup>164</sup>

Major depression is another differential diagnosis of dementia. Depression is often associated with reports of memory impairment, agitation and a reduction in intellectual abilities; consequently, the condition is often misinterpreted as dementia.<sup>64,176</sup> It should be noted, though, that the two conditions are not mutually exclusive.<sup>176</sup> About 17% of people with Alzheimer's disease also have major depression.<sup>177</sup> Depression may sometimes be distinguished from dementia on the basis of an assessment of the course and onset of depressive and cognitive symptoms.<sup>64</sup> Patients with depression are usually identified by neuropsychological testing as by scales such as the Geriatric Depression Scale (Appendix C) and most will have a history of previously treated depressive episodes.<sup>119</sup>

#### **4.2 Behavioural and Psychological symptoms of dementia (BPSD)**

Baumgarten *et al.* defined behavioural disturbances as '*the outward manifestation of some underlying cognitive, psychological, or physiological deficit – regardless of aetiology – likely to cause stress to those caring for the patient.*'<sup>178</sup> Other terms used to describe behavioural disturbances include 'challenging behaviour', 'neuropsychiatric symptoms', 'behaviours of concern' and 'behavioural and psychological symptoms'. Behavioural and psychological symptoms occur in the overwhelming majority of residents in RACFs, reflecting the high rate of mental health disorders in this setting.<sup>15</sup> Although conditions such as depression and schizophrenia-like psychotic illnesses are associated with behavioural and psychological symptoms, it is well established that residents with dementia display higher rates of behavioural

disturbance than residents without dementia and that symptoms tend to worsen as dementia progresses.<sup>58,179,180</sup>

The first signs of dementia involve memory loss, but as the disease progresses, behavioural and psychological symptoms will emerge in up to 90% of people with dementia.<sup>15</sup> The umbrella term of ‘BPSD’ (Behavioural and Psychological Symptoms of Dementia) was introduced by the International Psychogeriatric Association (IPA) to replace the term ‘behavioural disturbance’ in people with dementia.<sup>96</sup> The IPA’s formal definition of ‘BPSD’ is: ‘*symptoms of disturbed perception, thought content, mood or behaviour that frequently occur in patients with dementia*’, and encompasses a broad spectrum of symptoms and signs<sup>181</sup> A comprehensive listing of BPSD is shown in Table 12. The severity of BPSD symptoms can vary considerably from person to person. This variation may be due, in part, to different underlying types of dementia but people with the same type of dementia may display different symptoms. In late-stage dementia, many forms of BPSD can be present irrespective of dementia type.<sup>100</sup>

**Table 12: BPSD<sup>179</sup>**

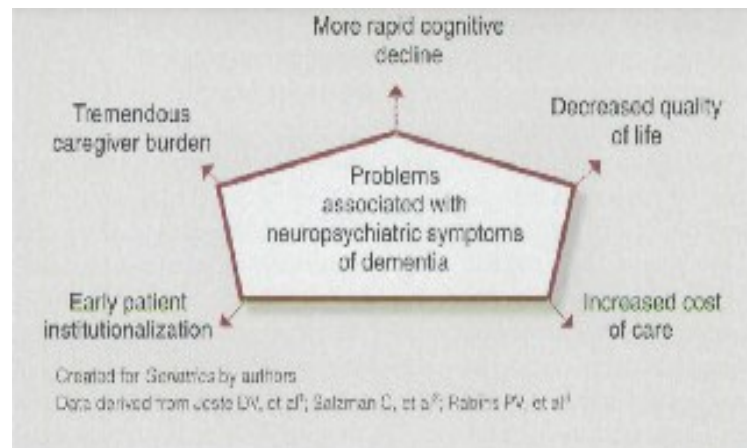
<b>Psychological symptoms</b>	<b>Behavioural symptoms</b>
anxiety	aggression
depressed mood	screaming
hallucinations	agitation
delusions	calling out
sleep disturbance	wandering
	hoarding
	shadowing (following carer closely)
	culturally inappropriate behaviour
	restlessness
	repetitive questioning

BPSD are perhaps the most distressing and difficult to manage features of dementia, resulting in major consequences for the sufferer, other residents and carers.<sup>182</sup> These symptoms are correlated with an increased rate of falls, disruption of night time sleep, and mortality.<sup>179,183</sup> More importantly, BPSD are associated with lower functional abilities, more rapid cognitive decline, earlier institutionalisation, an increased burden on caregivers and RACF staff, and higher costs of care (Figure 7).<sup>183</sup> For instance, when researchers tracked 210 people with dementia in the community they concluded that displaying behavioural symptoms shortened the time to residential care placement by approximately 2 years.<sup>184</sup>

Although the terminology and definitions associated with BPSD vary between countries, health authorities and researchers, there appears to be consensus that there are three main neuropsychiatric syndromes: agitation, psychosis and mood disorders.<sup>183</sup>



**Figure 7: Impact of behavioural and psychological symptoms of dementia<sup>182</sup>**



#### **4.2.1 Agitation**

The most commonly experienced BPSD is agitation; defined as *‘inappropriate verbal, vocal or motor activity unexplained by apparent needs or confusion’*.<sup>185</sup> Agitation refers to an array of behaviours that can be loosely classified as ‘disruptive but nonaggressive’, ‘socially inappropriate’ or ‘aggressive behaviour’, and is observed in up to 40-60% of residents in RACFs, with its highest expression in people with moderate to severe dementia.<sup>65,183,186</sup> ‘Aggression’, the extreme expression of agitation, is defined as: *‘hostile actions, directed towards others, the self or objects, and can be categorised further as physical, verbal or sexual’*.<sup>65</sup> Examples of aggressive behaviour include verbal abuse, hitting out, biting, and damaging property or physical violence towards another person.<sup>187</sup>

Verbally aggressive behaviours are most prevalent in the middle stages of dementia, when verbal abilities are still maintained but the ability to use them effectively is lessened.<sup>188</sup> In contrast, physically aggressive behaviours tend to occur in late stages of dementia, when verbal communication is severely compromised.<sup>188</sup> Several studies have found strong correlations between both psychosis and depression, and aggressive behaviour.<sup>15,189</sup> Symptoms of agitation and aggression tend to last longer than other BPSD, including psychosis and depression. In longitudinal studies, 50% or more of people with dementia experienced symptoms of aggression and agitation for periods longer than a year.<sup>183</sup>

#### **4.2.2 Psychosis**

Up to half of people with Alzheimer’s disease develop psychotic symptoms at some point in their illness.<sup>93</sup> These symptoms typically arise in the middle and late stages of the disease and persist for several months.<sup>93</sup> First-rank symptoms of schizophrenia almost never occur in people with dementia; instead less complex psychotic symptoms present, such as persecutory

delusions, visual and auditory hallucinations, which are all risk factors for aggression.<sup>15,96,183,190</sup> Delusions (i.e. fixed false beliefs) occur in about 30-40% of patients with dementia and are usually brief, variable and relapsing.<sup>118,188</sup> Patients with Alzheimer's disease often become suspicious of family members and may accuse them of stealing; believe that a spouse is an imposter, or that a long dead relative is alive.<sup>191</sup> Visual and auditory hallucinations also occur but are less common with an incidence rate of 20-30%<sup>118,191</sup> Some hallucinations, such as seeing an imaginary child playing on the floor, are non-threatening, whereas other hallucinations may precipitate aggressive behaviour.<sup>191</sup> Hallucinations in most people with dementia tend to be episodic in nature; however, dementia with Lewy bodies is associated with lengthy, cinematic-type visual hallucinations.<sup>118,191</sup>

#### **4.2.3 Mood disorders**

Depression occurs in at least 20% of people with dementia, with some researchers theorising that people with less severe dementia are at higher risk of developing depression.<sup>183</sup> However, this association could be due to difficulties detecting depression in the later stages of dementia.<sup>192</sup> Depression in people with dementia reduces quality of life (QOL), exacerbates cognitive and functional impairment, increases mortality and is associated with added carer stress and carer depression.<sup>183</sup> Far from typical presentations of flattened affect and apathy, depressive symptoms in dementia have been strongly linked with the development of aggression.<sup>15,189</sup> In fact, in a large cross-sectional study of U.S. RACF residents with dementia, both physical and verbal aggression were more strongly associated with depression than psychosis.<sup>189</sup> Brodaty *et al.* also reported a significant association between depressive symptoms and aggressive behaviour when he examined the predictors for aggressive behaviour in a sample of residents living in Australian RACFs.<sup>15</sup>

#### **4.3 Behavioural and psychological symptoms in RACFs**

Behavioural and psychological symptoms are extremely common in RACFs. During 1996 and 1997, Brodaty *et al.* surveyed all residents at 11 eastern-Sydney RACFs to gauge the prevalence of both dementia and behavioural symptoms using validated scales.<sup>15</sup> A total of 92% of residents were classified as displaying at least one behavioural symptom on the behavioural scale; Behavioural Pathology in Alzheimer's Disease (BEHAVE-AD).<sup>15</sup> What is interesting to note is that the majority of residents without dementia also displayed behavioural and psychological symptoms (84%), highlighting that these symptoms are not exclusively the domain of people suffering from dementia.<sup>15</sup> Several other international studies have assessed the prevalence of behavioural and psychological symptoms in residential aged care settings over the last decade (summarised in Table 13).<sup>15-17,193,194</sup> In spite of differences in resident mix and health care structure, all published studies report a high prevalence rate in RACF settings.

On average, about one in three residents displays psychotic symptoms, at least one in four exhibits aggressive behaviours and up to half has depressive symptoms. In terms of symptom severity, in a survey of a representative sample of more than 10 000 residents of Australian hostels and RACFs, nursing staff rated 32% of residents as having mild behavioural disturbance, 22% as moderate, and 14% as severe.<sup>46</sup>

**Table 13: International RACF studies of behavioural and psychological symptom prevalence in RACFs<sup>15-17,193,194</sup>**

Study	Country	≥1 BPSD	delusions	Halluci - nations	Depressive symptoms	Agitation	Aggression	Anxiety	Insom nia
Brodarty et al 2001(n=647)	Australia	92%	54%	33%	44%	n/a	76%	69%	47%
Pitkala et al 2004(n=160)	Finland	88%	36%	36%	51%	27.5%	17.5%	51%	26%
Selbaek et al 2007(n=1163)	Norway	74%	31%	22%	41%	(35%	combined)	29%	n/a
Zuidema et al 2007(n=1322)	Holland	81%	15%	8%	20%	(31%	combined)	21%	12%
Wu et al 2009(n=148)	Australia, China	n/a	43%	35%	52%	(64%	combined)	43%	36%

#### **4.3.1 Impact of behavioural symptoms on relatives, carers and nursing staff**

Behavioural symptoms that require constant supervision or involve aggressive acts are associated with greater levels of caregiver burden.<sup>93</sup> In addition, the number and severity of disturbed behaviours also correlates strongly with higher levels of caregiver stress.<sup>188</sup> Amongst carers themselves, the challenge of providing care is associated with depression, a greater number of GP visits and increased prescription drug usage.<sup>25</sup> Although the majority of families and carers of people with dementia wish to avoid premature entry into residential care, behavioural symptoms are strongly associated with increased risk of institutionalisation.<sup>195</sup>

Once in residential care, behavioural and psychological symptoms also affect nursing staff, causing distress and these symptoms impact significantly on workload and retention rates.<sup>25</sup> The negative impact of some of the behaviours, particularly aggressive behaviour, may lead to: increased absenteeism of nursing staff, security costs, workers' compensation, reduced job satisfaction, recruitment and retention issues.<sup>196</sup> In a 2005 cross-sectional survey of over 250 Tasmanian nursing staff at 15 RACFs, over 80% of staff reported residents' repetitive actions, wandering and verbal outbursts as occurring more than once a day.<sup>196</sup> Residents' physical

aggression, verbal disruptions and wandering were ranked 1, 2 and 3, respectively, as causing staff the most personal distress.<sup>196</sup>

#### **4.4 Evaluation of BPSD**

In general, guidelines suggest that BPSD should not be treated as a monolithic syndrome but with specific identification (e.g. apathy, wandering, delusions) and detailed descriptions of each targeted behaviour.<sup>25</sup> A clear definition of the specific problem behaviour to be addressed is the first step to modifying the behaviour.<sup>93</sup> One recommendation for caregivers is to maintain a log, carefully observing and documenting the intensity, frequency, precipitants, and consequences of target behaviours.<sup>182,197</sup> The impact of the behaviour on the resident and caregivers should also be observed and documented.<sup>113</sup> Such ‘behavioural mapping’ helps to characterise symptoms, is critical to revealing the cause or trigger of the behaviour, can help guide treatment planning and assist in the monitoring of treatment effectiveness.<sup>64,182,198</sup>

##### **4.4.1 Screening tools for behavioural and psychological symptoms**

Many RACFs regularly screen residents to detect behavioural symptoms that warrant further detailed investigation, to obtain an objective measure of the severity and duration of symptoms, as well as to monitor treatment strategies already in place.<sup>65,199</sup> There are several validated behavioural assessment scales used in RACFs and these scales are also frequently used by researchers.<sup>182</sup> A standardised scale for the general assessment of behavioural symptoms is the Cohen-Mansfield Agitation Inventory (CMAI) (Appendix D) which is a caregiver questionnaire and rates various agitated behaviours on a 7-point scale of frequency, ranging from “never” to “several times an hour.”<sup>185</sup> Another scale for rating behaviour in dementia is the Neuropsychiatric Inventory (NPI)(Appendix A).<sup>200</sup> Usually administered by a health professional, the NPI also measures the distress the symptom causes the caregiver.<sup>200</sup> Of the two behavioural scales, the NPI is the most widely used in clinical practice.<sup>201</sup>

##### **4.4.2 Detailed investigation of BPSD**

The next step of evaluation is the investigation of any underlying factors that precipitate or exacerbate the target BPSD.<sup>65,182</sup> Agitation and other behaviours can result from a medical condition such as an infection, undertreated pain, constipation, dehydration or worsening of a medical condition.<sup>65,96,182</sup> For example, in a U.S. chart review of 408 residents, investigators found that verbal agitation in residents had significant associations with pain and physical illness.<sup>199</sup> Such medical symptoms may not be articulated by the resident or recognised by caregivers.<sup>93</sup> For this reason, when evaluating behavioural symptoms and identifying treatable medical causes, a detailed medical history, physical exam and follow-up investigations are recommended.<sup>65,96</sup>

It is important to seek, evaluate and rule out any co-morbid psychiatric conditions such as delirium, depression, anxiety, sleep disorder or psychosis, as newly identified or worsened psychiatric disorders may trigger behavioural symptoms.<sup>93,198</sup> Medications can also worsen cognitive impairment and aggravate BPSD (Table 14). For this reason, a careful medication review should be conducted when BPSD is assessed.<sup>201</sup>

**Table 14: Selected medications that may cause or contribute to BPSD<sup>202</sup>**

<b>Drug</b>	<b>Reaction</b>	<b>Comments</b>
Anticholinergics	Confusion, memory loss, delirium, Hallucinations, agitation, fear	<i>more frequent in elderly with high doses</i>
Anticonvulsants	Agitation, confusion, delirium, Depression, psychosis, aggression	<i>usually with high doses or high plasma levels</i>
Benzodiazepines	Delirium, hostility, paranoia	<i>during treatment or withdrawal</i>
H2 antagonists	Delirium, confusion, psychosis, mania	<i>occurs more frequently with cimetidine</i>
Tricyclic antidepressants	Mania, delirium, anticholinergic Effects, paranoia, hallucinations	<i>more frequent in elderly with high doses</i>

Environmental and social factors can also contribute to BPSD including:

- Situational factors such as changes in staff
- Poor communication between the resident and caregivers
- Inadequate recognition and management of sensory impairments
- Changes from normal life patterns, preferences and autonomy
- Changes in the physical environment such as changes in room.<sup>65,203,204</sup>

#### **4.5 Aetiology of BPSD**

The causes underlying the development of BPSD are unclear. Proposed theories to explain why BPSD emerge include both psychosocial as well as biological causes. The psychosocial theories hypothesize that BPSD are caused by various factors, which has led to various non-drug, psychosocial and environmental treatments.<sup>197</sup> Alternatively, pharmacological theories have focused on the effects of neurological damage to neurotransmitter systems which have led to drug treatments.<sup>197</sup> Unfortunately, neither the psychosocial nor the pharmacological theories have been sufficient to explain the diverse and wide range of symptoms, nor have either theorem provided a rationale for therapies that are markedly effective for the majority of people with BPSD.<sup>197</sup>

#### **4.5.1 Theoretical psychosocial models to understand BPSD**

A number of conceptual models have been developed to understand why behaviours in dementia eventuate. These models are helpful for care staff because they provide guidance for detecting the cause of behavioural symptoms, help them understand the meanings of behaviours and provide the basis for different interventions.<sup>179,205-207</sup> The models are not mutually exclusive and can be used in conjunction with each other.<sup>205,207</sup> Three main behavioural models are outlined briefly as follows:

a) The person-centred approach model: The concept of person-centred care acknowledges that a person is an individual who can experience life and relationships, despite the dementia.<sup>208</sup> The person-centred approach model offers and respects choices, recognises the person's past life, and focuses on what the person can do, rather than lost abilities.<sup>208</sup> The model focuses on attempting to understand behaviour, maximising each person's potential and shared decision making (Table 15).<sup>205,208</sup> Evidence supporting the person-centred approach model includes a large British trial which showed that training staff in person-centred care principles resulted in significantly fewer antipsychotic medications being given to the intervention group after 12 months.<sup>209</sup> Likewise, in two recent RACF studies in France and Norway, when nursing staff were educated about the non-pharmacological BPSD management, there were significant decreases in the CMAI scores of residents.<sup>210,211</sup> Finally, in Australia, when Chenoweth *et al.* carried out a RCT of person-centred care in 15 RACFs, with nursing staff in intervention facilities receiving training and support, CMAI scores were lower in those facilities providing person-centred care.<sup>212</sup>

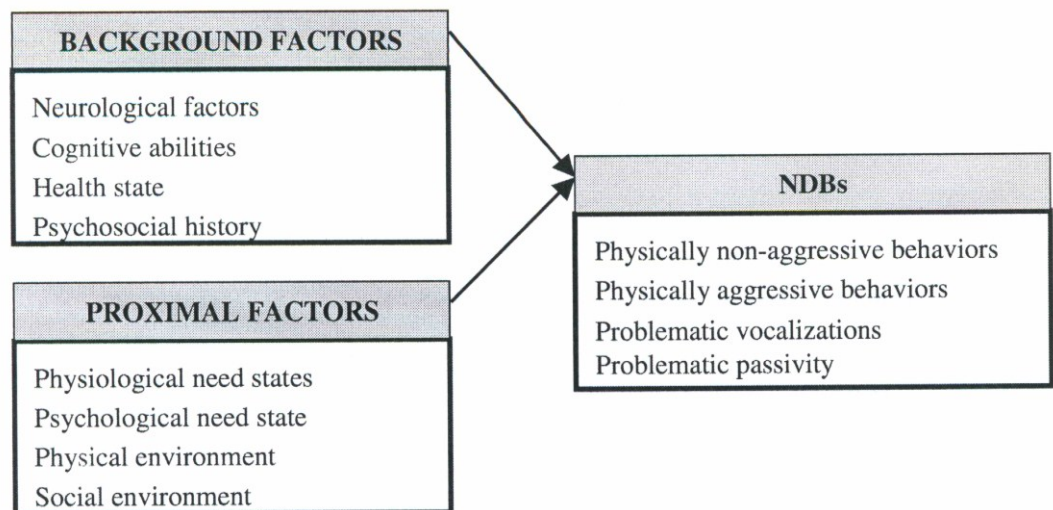
**Table 15: Components of person-centred care for people with Alzheimer's disease<sup>208</sup>**

- 
- |   |
|---|
| <ul style="list-style-type: none"> <li>• Regard personhood in people with AD as increasingly concealed rather than lost</li> <li>• Acknowledge the personhood of people with AD in all aspects of care</li> <li>• Personalise care and surroundings</li> <li>• Offer shared decision making</li> <li>• Interpret behaviour from person's viewpoint</li> <li>• Prioritise the relationship to the same extent as the care tasks</li> </ul> |
|---|
- 

b) The need-driven dementia-compromised behavioural model (NDB): The NDB model views behaviours of dementia from the perspective of the person with dementia.<sup>206</sup> Behaviours stem from a need or goal and are an attempt to convey meaning.<sup>179,206</sup> In the model the interaction of two 'factors' produces the 'need-driven' behaviour (Figure 8).<sup>213</sup> *Background* factors are characteristics of the person, including the extent of neurological damage and psychological history.<sup>213</sup> *Proximal* factors, on the other hand, are more immediate cause of behaviours, specifically, variables such the environment.<sup>206,213</sup> The NDB model recognises that

it is difficult to influence background factors, but that proximal factors are able to be modified.<sup>206</sup> Non-pharmacological strategies should target proximal factors predominantly, and involve an understanding of un-met needs while catering to the resident's individual abilities and preferences.<sup>214</sup>

**Figure 8: The need-driven compromised behaviour model<sup>206,213</sup>**



a) ‘Antecedent-Behaviour-Consequence’ (ABC) model: This final model presumes that a person's behaviour can be charted using the Antecedents – Behaviour – Consequences method (ABC) which helps to identify behaviour patterns and events that caused them. The ‘A’, ‘B’ and ‘C’ are defined as:

*Antecedent*: an observable stimulus or condition in the person's environment leading up to the behaviour. The Antecedent can be external (e.g. lighting and particular people) or specific to the person (e.g. pain, medication or loneliness).<sup>110</sup>

*Behaviour*: an observable response / action to the antecedents.<sup>110</sup>

*Consequences*: result from the behaviour and can be either reinforcing or punishing. Many problem behaviours are learned through reinforcement by carers who give attention when the unwanted behaviour is displayed.<sup>107</sup>

The ABC model instructs care staff to identify antecedents of a specific behaviour as well as clearly define the behaviour's consequences.<sup>206</sup> To alter behaviour, care-staff need to change either the antecedents or the consequences of the behaviour.<sup>206,215</sup> For example, one of the antecedents may be pain and analgesic administration may remove the stimulus, thus improving behaviour. One of the consequences of behaviour in RACFs is thought to be increased attention

when problem behaviour is displayed.<sup>216</sup> Rewarding quiet behaviour with small rewards and ignoring problem behaviours is theorised to discourage problem behaviours.<sup>207</sup>

#### **4.6 The non-pharmacological management of BPSD**

After a comprehensive assessment of a targeted behaviour, non-pharmacological interventions are recommended ‘first-line’ when managing behavioural and psychological symptoms.<sup>14,93</sup> Traditionally, however, BPSD have been managed preferentially by medication, and non-pharmacological behavioural approaches are under-utilised in RACFs.<sup>14</sup>

There are two main advantages of using non-pharmacological interventions. Firstly, this approach aims to address the psychosocial/environmental reasons for the behaviour and secondly, the limitations of pharmacological treatment are avoided, namely side effects, drug interactions and limited efficacy.<sup>207</sup> Before introducing an intervention the goals of care should be negotiated.<sup>207</sup> It is vital to emphasise that the targeted behaviour often cannot be eliminated completely but it may be reduced to tolerable levels.<sup>217</sup> The American Psychiatric Association (APA) divides non-pharmacologic or psychosocial treatments for dementia into four broad groups: behaviour oriented, emotion oriented, cognition oriented, and stimulation oriented.<sup>64</sup>

##### **4.6.1 Behaviour-oriented approaches**

Behavioural interventions incorporating reinforcement have shown modest benefit in small trials and single case studies.<sup>64</sup> For example, the results of a small randomised controlled study of a four-session aggression behaviour-management training program for caregivers showed a trend towards lower rates of aggression in the intervention group ( $P = 0.07$ ).<sup>218</sup> Some researchers feel strongly that behaviour modification is not feasible in people with dementia as learning is severely impaired.<sup>205,216</sup> Research evidence for the effectiveness of the behavioural interventions is limited and some researchers argue that the reported benefits derive from increased attention from care staff rather than the learned consequences of challenging behaviour.<sup>205,216</sup>

##### **4.6.2 Emotion-oriented approaches**

Emotion-oriented interventions are focused on increasing pleasure to improve mood and behaviour, and include reminiscence therapy, validation therapy and simulated presence therapy.<sup>64,219</sup> Reminiscence therapy aims to stimulate memory and improve mood in the context of the resident’s life history by the use of pictures, music and scrapbooks.<sup>64,205</sup> This therapy has been associated with short-lived gains in mood and behaviour in several studies with ‘confused’ older people; however a Cochrane review concluded that there is not sufficient evidence to classify reminiscence therapy as effective for people with dementia.<sup>220</sup> Likewise, validation



therapy, which aims to reduce stress by validating non-verbal expressions of emotion, was not considered to have sufficient evidence of effectiveness in another Cochrane review.<sup>221</sup>

Simulated presence therapy recognises that visits by relatives to RACFs often provide comfort for residents with dementia.<sup>222</sup> The basis for this therapy is that family members record personalised conversations on audiotape or videos.<sup>179</sup> The person with dementia then listens to or views the simulated tapes when agitated.<sup>179</sup> Two studies have shown that agitated behaviour decreased significantly during the simulated presence of a family member compared to a placebo recording or usual care.<sup>223,224</sup> Camberg *et al.* reported reductions in agitation 67% of the time during simulated presence compared to reductions 46% of the time for placebo.<sup>223</sup> In a more recent study, Garland *et al.* reported that rates of physical and/or verbal agitation fell by 43% in about half of the residents during simulated presence and that the therapy was also effective in reducing withdrawn behaviours.<sup>142</sup>

#### **4.6.3 Cognitive-orientated approaches**

Cognitive-orientated approaches include reality orientation and skills training which aim to restore cognitive deficits.<sup>64</sup> Reality orientation assists residents to be more aware of themselves in relation to the environment and time by providing items such as photographs, large calendars and labels on doors.<sup>203</sup> Several studies have demonstrated mild, short-term improvement in measures of cognition, function and behaviour with this approach.<sup>64</sup> For example, in a British single-blind, multicentre controlled clinical trial comparing a cognitive stimulation program with routine care for 201 people with dementia, improvements were recorded in MMSE, ADAS-Cog and in quality of life scores.<sup>225</sup> It should be noted though that cognitive-orientated approaches are not suited to residents with advanced dementia where cognitive faculties are much diminished.<sup>219</sup> Cognitive strategies have also been associated with reports of frustration in participants and depression in caregivers.<sup>64</sup>

#### **4.6.4 Sensory Stimulation-oriented approaches**

Sensory stimulation treatments stimulate the senses and are intended to provide enrichment of the resident's environment.<sup>64,219</sup> Examples include recreational activities (e.g. crafts, pets, exercise), music, multisensory stimulation, bright-light therapy and aromatherapy.<sup>44</sup> Structured and unstructured activities with individuals or groups involving tasks such as sorting, cooking and gardening are theorised to reduce agitation and improve quality of life.<sup>65</sup> However, surprisingly few studies have examined the impact of participation in activities programs on problem behaviours.<sup>207,226</sup> A small study of 15 residents found recreational interventions including manipulative (e.g. bead maze), nurturing (e.g. doll), sorting (e.g. puzzles), sewing (e.g. lace cards) and sound/music alleviated agitated behaviour in 57% of episodes.<sup>227</sup> Pet therapy has also shown some benefit on behaviour of residents in residential care. In one study,

half-hour sessions with a dog resulted in significantly lower levels of agitation than half-hour sessions with only the researcher present.<sup>228</sup> Outdoor walks have also led to beneficial effects in people with dementia. For instance, Holmberg reported a 30% reduction in aggressive incidents on days when residents were taken for group walks compared to days without walks.<sup>229</sup>

#### *4.6.4.1 Music*

One of the most tested interventions for the non-pharmacological management of BPSD is the use of music for either stimulation or relaxation.<sup>222,207</sup> Music has been reported to relieve anxiety and agitation, increase attention span, increase socialisation and social skills in patients with dementia.<sup>188</sup> In one RACF study, when background soothing music was played during bathing, counts of physical aggression fell 42% more during music sessions than control sessions without music ( $p < 0.05$ ).<sup>230</sup> The type of music and the way the music is presented appears to influence the effectiveness of this type of therapy. For example, Gerdner assessed behaviour of 39 agitated residents during and immediately after exposure to classical ‘soothing’ music or resident’s ‘preferred’ music.<sup>231</sup> Rates of agitated behaviours fell from baseline by 49% during classical music as opposed to a 61% reduction when ‘preferred’ music was played.<sup>231</sup>

#### *4.6.4.2 Multi-sensory stimulation*

Multi-sensory stimulation (MSS) refers to a combination of stimuli delivered to different sensory modalities including hearing, touch and smell.<sup>207</sup> One of the most well known programs that incorporates this approach is ‘Snoezelen’, a dutch intervention that combines soft music, aromatherapy, textured objects and coloured lighting in a designated room.<sup>65</sup> In a Cochrane review, it was noted that ‘Snoezelen’ could have positive immediate effects on apathy, restlessness and repetitive behaviours.<sup>232</sup>

#### *4.6.4.3 Bright-light therapy*

Fragmented sleep-wake cycles in dementia can be associated with aberrant behaviours.<sup>219</sup> Bright-light therapy (BLT) aims to improve sleep, thus reducing agitation, and involves a person sitting in front of a light box with the entire visual angle exposed to the light source.<sup>183,207</sup> The amount of light is up to 10 000 lux, compared to office light, which is up to 300 lux.<sup>183</sup> Forbes *et al*’s Cochrane review concluded that there was insufficient evidence to support the use of this therapy and that further trials were needed.<sup>233</sup> Subsequent to this review, a recent trial exposed ten participants with severe dementia to morning bright lights for 45 minutes each morning for four weeks.<sup>234</sup> A significant reduction in aberrant behaviour was reported.<sup>234</sup> It is theorised that a biological mechanism involving hypothalamus stimulation may be responsible for the calming actions.<sup>183</sup>

#### *4.6.4.4 Aromatherapy*

Another non-pharmacological therapy that is theorised to have a direct biological action is aromatherapy, mediated through volatile constituents (terpenes) which are thought to modulate neurotransmitter action.<sup>183,222</sup> Aromatherapy involves the diffusion of aromatic oil into the environment either by inhalation or skin application. The two oils that have been used in trials are Lemon-balm (*Melissa*) and lavender oil.<sup>183,219</sup> Lin *et al.* reported significant reductions in agitation and aberrant motor behaviours in a RACF when lavender oil was administered via a diffuser compared to placebo.<sup>235</sup> Ballard *et al.* examined the effects of lemon balm or sunflower oil massaged lightly on the face and arms of 71 residents with severe dementia.<sup>236</sup> CMAI scores (discussed in section 3.4) were significantly reduced by 35%, on average, versus an 11% reduction for the sunflower oil ( $p < 0.0001$ ).<sup>236</sup>

#### **4.6.5 Limitations and barriers of the non-pharmacological management of BPSD**

In the RACF setting, studies of non-pharmacological interventions outnumber studies of medication.<sup>199</sup> However, recent reviews have concluded that the quality of evidence is often poor in the majority of studies, with sample sizes too small and methodologies weak.<sup>219,222,237-239</sup> Other criticisms are that many non-pharmacological studies test strategies on participants with mild symptoms, adverse outcomes are rarely systematically evaluated and studies are often of limited duration.<sup>64,182</sup>

It is difficult to compare outcomes resulting from drug and non-drug treatments directly. Drug companies have access to much greater levels of funding to test new drug treatments than is available for testing non-drug strategies, meaning large multi-site randomised controlled trials of drug treatment can be performed, whereas these sort of trials are not feasible with non-drug therapies.<sup>207</sup> It is also important to recognise that a lack of rigorous research is not equal to a lack of efficacy.<sup>182</sup> Several researchers stress that despite the absence of large placebo randomised controlled trials as in drug trials, there is quality research literature providing an expanding database of evidence to support non-pharmacological approaches.<sup>183,207</sup> Often the combination of the results of several studies showing the same trends lends support to non-pharmacological approaches.<sup>207</sup>

Of the psychosocial interventions described, individually tailored interventions, whether to music, activity or conversation appear to be the most effective.<sup>222,239</sup> Social interaction, especially human interaction, seems to work best of all. Cohen-Mansfield and Werner compared one-to-one social interaction with music and simulated presence therapies, reporting that social interaction was more effective at reducing aberrant behaviour.<sup>240</sup> One-to-one interaction is an element of care that is in short supply in many RACFs, where staff are often busy, stressed, under-trained and poorly remunerated.<sup>122</sup> There are many barriers to the implementation of non-drug interventions for BPSD management. One of the main barriers is the lack of financial

resources to incorporate such strategies into day-to-day practice.<sup>207</sup> Furthermore, although medications for behavioural management in people with dementia are heavily subsidised, none of the non-drug interventions qualify for government subsidies.<sup>207,222</sup> Other barriers include a lack of knowledge and training regarding non-drug therapies in caregivers, inadequate staffing levels and the perception that medicines are simply easier to administer.<sup>207,241</sup>

#### **4.7 Use of psychotropic medication to manage BPSD**

Although the majority of clinical guidelines recommend the use of non-pharmacological strategies for the initial treatment of BPSD, anxiety and sleep disorder there is strong evidence that psychotropic medications are frequently used in RACFs to treat these symptoms.<sup>38,39,58,164,242-244</sup>

##### **4.7.1 The ‘pharmacological’ model to understand BPSD**

In marked contrast to the psychosocial models used to explain why BPSD occur, the ‘pharmacological model’ views BPSD as the ‘more or less random consequence of neurological damage’, and considers that the best approach to manage behaviour is to use psychotropic medications.<sup>205,206</sup> There is limited research as to the neurobiological basis of BPSD but it is theorised that there are associations between agitation and frontal cholinergic deficits in Alzheimer’s disease, and between visual hallucinations and temporal cortex cholinergic deficits in dementia with Lewy bodies.<sup>183</sup> Other researchers suggest that the loss of noradrenergic and serotonergic receptors may also be associated with agitation and depression.<sup>163,183</sup> Finally, there may also be an association between alterations in dopaminergic function and psychosis.<sup>183</sup> It is postulated that different symptoms in BPSD may involve different neurotransmitter systems, thus providing an explanation why some symptoms are drug responsive, such as anxiety, agitation and psychosis; whereas symptoms including wandering and screaming appear to be unresponsive to all medication (Table 16).<sup>163</sup>

**Table 16: Behaviours that respond poorly to pharmacological treatment<sup>245</sup>**

Wandering
Pacing
Entering rooms uninvited
Attempting to leave
Making disruptive vocalisations
Voiding inappropriately

One of the main disadvantages of the pharmacological approach as opposed to psychosocial approaches is that it focuses on using medication to reduce behaviours rather than assisting people with dementia to interact with others or get their needs met.<sup>205</sup> Moreover, it is argued that

the pharmacological approach can deny the personhood of the individual and leave them prone to damaging side effects, often without appreciable benefit.<sup>205</sup>

Multiple classes of medications have been used to treat BPSD; however, like for non-pharmacological treatment, the evidence base for the drug treatment of BPSD is poor.<sup>163,182</sup> Although various psychotropic agents are routinely used as treatments for BPSD, the majority of these drug classes are not licensed for this indication and there is limited information about effectiveness and safety.<sup>163,241</sup> Sink *et al.* in a comprehensive review of pharmacological agents used to treat BPSD concluded that, overall '*there is no clear consensus or standard of care*'.<sup>246</sup>

#### **4.8 Antipsychotics to treat BPSD**

The most commonly used and best studied drug class to manage BPSD are antipsychotic drugs. The initial prescribing of these agents was motivated by observations that psychosis is present in many people with dementia.<sup>110</sup> However, the mechanism responsible for psychosis in dementia is not well defined and, in all probability, differs from the mechanism hypothesised for psychotic disorders such as schizophrenia for which antipsychotic medications were designed.<sup>110</sup> This may help explain why antipsychotic efficacy to treat psychosis in dementia is modest.<sup>64,197,199</sup>

##### **4.8.1 Effectiveness of typical antipsychotics to treat BPSD**

From the 1950s to the mid-1990s, the typical antipsychotics, including haloperidol, chlorpromazine and thioridazine were the primary pharmacological treatments for BPSD.<sup>163</sup> In 1990, Schneider *et al.* published a meta-analysis of controlled clinical trials of typical antipsychotics in agitated dementia patients.<sup>47</sup> Only seven trials met the inclusion criteria, involving 252 patients.<sup>64,247,248</sup> Schneider *et al.* concluded that typical agents produce a small effect size of improved behaviour in 18% more patients treated than placebo, and also stated that '*no single neuroleptic is better than another*'.<sup>248,249</sup> Adverse effects and dropouts were common, however specific rates were not recorded.<sup>64,247</sup>

In a later meta-analysis of typical antipsychotics incorporating the results of 16 controlled clinical trials, a 26% effect size in clinical improvement was reported, and again, there was no significant difference detected in efficacy between different antipsychotics.<sup>250</sup> Significant side effects, principally EPS, were found in 25% more treated patients than those who received placebo, leaving the researchers to conclude that efficacy rates of antipsychotics were roughly equivalent to adverse events rates.<sup>250</sup>

Haloperidol, a typical antipsychotic, is widely used in people with dementia due to its low incidence of sedation and anti-cholinergic effects. A 2002 Cochrane review examined the evidence for the use of haloperidol to control agitated dementia.<sup>251</sup> In the 5 randomised controlled trials that met inclusion criteria, involving a total of 856 dementia patients,

haloperidol was found to have no significant effect on behavioural symptoms as a whole.<sup>251</sup> There did, however, appear to be a modest benefit in aggression, at doses of 1.2 - 3.5 mg/day.<sup>251</sup> On the other hand, dropouts due to adverse effects such as EPS and sedation were twice as likely to occur amongst those patients randomised to haloperidol than placebo.<sup>251</sup>

Although lower potency typical antipsychotics such as chlorpromazine and trifluoperazine are associated with a lower rate of EPS, these medications have strong anticholinergic properties which make them less suitable options for older adults with dementia, given that central cholinergic deficit is associated with cognitive impairment.<sup>100</sup> Apart from movement related effects, other side effects associated with typical antipsychotic use in people with dementia include sedation, postural hypotension, falls and QT interval prolongation.<sup>163,252</sup>

#### **4.8.2 Effectiveness of atypical antipsychotics to treat BPSD**

The first major meta-analysis evaluating the effectiveness of the atypical antipsychotics in dementia was published in 2006 by Schneider *et al.*<sup>112</sup> Fifteen double-blind placebo-controlled trials were included in the review, with trials lasting from 6-12 weeks.<sup>112</sup> A total of 3353 patients were randomised to antipsychotic treatment and 1757 were randomised to placebo.<sup>112</sup> On average, the overall treatment effect on aggression and/or psychosis was 18%; an identical effect size to that reported for typical antipsychotics.<sup>109,247</sup> In addition, atypical antipsychotics were about three times as likely as placebo to cause adverse effects, including sedation, falls, EPS, peripheral oedema and infections.<sup>112,253</sup>

In 2006, a Cochrane review evaluated 16 placebo-controlled trials investigating the efficacy of atypical antipsychotics to treat BPSD.<sup>254</sup> In summary, the review found:

- A modest significant improvement in aggression with risperidone and olanzapine compared to placebo.
- A modest significant improvement in psychosis with risperidone compared to placebo.
- Antipsychotic therapy was associated with a significant increase in somnolence, falls, urinary tract and respiratory infections and peripheral oedema. The risk of all these side effects was dose-related.
- Both risperidone and olanzapine patients had a significantly higher incidence of cerebrovascular events and EPS (especially risperidone at daily doses >1mg).<sup>163,190,254</sup>

A non-industry, randomised, double-blind, placebo-controlled trial, the CATIE-AD (Clinical Antipsychotic Trial of Intervention Effectiveness – Alzheimer’s Disease) trial utilised a novel ‘real world’ design to compare the effectiveness of atypical antipsychotics and placebo in 421 community-dwelling participants with Alzheimer’s disease and either psychosis or

aggressive behaviour.<sup>253,255</sup> Participants were randomised to olanzapine, risperidone, quetiapine or placebo, physicians could adjust the dosage throughout the trial, and participants could continue therapy for up to 36 weeks.<sup>110,255</sup> If the participant's response was inadequate for any reason after the first two weeks of therapy, treatment could be ceased.<sup>110</sup> The primary outcome of CATIE-AD was time to discontinuation of treatment for any reason.<sup>110</sup> CATIE-AD reported no significant difference between any of the treatments or placebo, with median treatment durations ranging between 5.3 and 8.1 weeks.<sup>255</sup> The percentage of participants who responded did not differ significantly for olanzapine (32%), risperidone (29%), quetiapine (26%), and placebo (21%, overall  $P=0.22$ ).<sup>255</sup> Adverse effects accounted for discontinuations in 24%, 18% and 16% of participants taking olanzapine, risperidone and quetiapine, respectively; as opposed to 5% of people taking placebo.<sup>109,255</sup>

The use of atypical antipsychotics has been associated with weight gain and metabolic abnormalities such as hyperglycaemia in younger schizophrenic patients.<sup>110</sup> CATIE-AD was the first trial to examine this association in older people with dementia, reporting that participants taking olanzapine, quetiapine and risperidone averaged a monthly weight gain of 1.0, 0.7 and 0.4 pounds, respectively, on treatment, compared to weight loss among participants taking placebo.<sup>255,256</sup> Furthermore, none of the atypical antipsychotics improved function, quality of life or caregiver burden.<sup>257</sup>

Although a landmark trial, several limitations have been highlighted regarding the CATIE-AD trial.<sup>109,110</sup> Firstly, the dose of quetiapine used in the trial may have been sub-therapeutic at doses of 25mg to 50mg per day (Recommended doses are not available as quetiapine is not licensed to treat BPSD but doses used in other quetiapine trials to manage BPSD range from 100mg to 200mg per day).<sup>258</sup> Further, the discontinuation rates were higher than those found in similar trials, possibly due to trial design where 'non-responders' could easily move onto phase 2 of the study. Finally, it should be noted that the participants of CATIE-AD were rated as having mild to moderate dementia and were all community based. The findings, therefore, cannot be generalised to a RACF population of residents with more advanced dementia.<sup>110</sup>

In his recent U.K. report, 'The use of antipsychotic medication for people with dementia: Time for action', Professor Banerjee, concluded that the effect size on BPSD for most atypical antipsychotic drugs was minimal and that the number of patients needed to treat to achieve clinically significant improvement in one additional behaviourally disturbed patient ranged from 5 to 11.<sup>259</sup> Banerjee's report stresses that there is limited data on the efficacy of antipsychotics for BPSD beyond 8-12 weeks, although acknowledging these drugs are often used for much longer periods.<sup>64,259,260</sup>

Even though the majority of meta-analyses conclude antipsychotics are only modestly effective to treat BPSD, it is relevant to note that subgroup analyses across trials indicate that

larger effect sizes are associated with greater cognitive impairment, residence in RACF and the presence of severe agitation at baseline.<sup>110,112</sup>

#### **4.8.3 Safety of antipsychotic treatment for BPSD**

Although it is widely established that antipsychotic use is associated with EPS, sedation, falls, anti-cholinergic effects, cardiac conduction abnormalities, metabolic abnormalities, infections and peripheral oedema, during the last decade two very serious adverse events have been linked to antipsychotic use, specifically in people with dementia; cerebrovascular events and death.<sup>109,261,262</sup>

##### *4.8.3.1 Cerebrovascular risk*

The association between antipsychotics and cerebrovascular adverse events (CVAE), mainly stroke and transient ischaemic attacks (TIAs), was first reported in an Australian trial which evaluated risperidone for BPSD.<sup>100,190,263</sup> Brodaty *et al.* conducted a RCT in 345 patients with BPSD where participants were randomised to receive, for a period of 12 weeks, a flexible dose of either placebo or risperidone solution up to a maximum of 2mg/day.<sup>240</sup> Six patients in the intervention group experienced a CVAE while none occurred in the placebo group.<sup>263</sup> De Deyn *et al.* in a review of risperidone RCTs found a total of 29 (3.9%) CVAEs with risperidone treated patients as compared to 7 (1.6%) in placebo-treated patients.<sup>264</sup> CVAEs were reported at an average of 30.7 days after beginning treatment with risperidone and 56.7 days for placebo, and the incidence of CVAEs did not appear to be dose dependent.<sup>264</sup>

When the U.K. Committee of Safety of Medicines (CSM) combined data from three separate RCTs, risperidone was associated with a threefold increased risk of serious CVAE compared to placebo (OR 3.6, 95%CI 1.7-7.7  $p < 0.005$ ).<sup>265</sup> Shortly after, a similar increase in the risk of CVAEs was linked to olanzapine and aripiprazole use.<sup>64,109</sup> A Meta-analysis of 15 RCTs of dementia patients treated with atypical antipsychotics found that there were 63 versus 16 CVAE events in antipsychotic and placebo patients, respectively, among 3 327 patients taking antipsychotic drugs and 1 728 patients on placebo. There was an increased odds ratio (OR) by meta-analysis for CVAEs of 2.13; (CI 1.60-3.75;  $P = 0.009$ ), 1.9% vs. 0.9% pooled.<sup>112</sup> There was a significantly increased risk of CVAE with risperidone OR = 3.43; (CI 1.60-7.32;  $P = 0.001$ ), 3.1% vs. 1.0% pooled.<sup>112</sup>

The mechanism/s underlying the increased risk of CVAE are unknown but possible theories involve metabolic changes, conduction abnormalities and sedation leading to venous stasis.<sup>109,266</sup> The relationship of antipsychotic dose to CVAE risk is also unclear: however, there is some evidence to suggest that the risk is highest in the first few weeks of use and that patients with vascular dementia and/or a history of CVAE are at greater risk.<sup>109,259,262</sup>



As a consequence of this increased risk of stroke and cerebrovascular event, various drug safety organisations issued warnings about the potential increased risk of CVAEs associated with atypical antipsychotics, resulting in some prescribers switching their patients over from atypical to typical antipsychotics.<sup>100</sup> However, shortly after the initial safety warnings were issued, a Canadian retrospective cohort study following 32 710 older patients with dementia found that patients receiving typical antipsychotics had a similar, if not higher, stroke risk to those patients taking atypical antipsychotics.<sup>267</sup>

In a recent comprehensive review of the literature, a total of 22 studies were found that evaluated the risk of CVAEs. Of these 22 studies, only 2 were placebo-controlled, the remainder were population based studies or retrospective analysis.<sup>262</sup> The available data indicate that the risk of CVAEs is higher in those people with dementia treated with antipsychotics by about 1.3 to 2 times. It appears that the risk for CVAEs is similar for atypical and typical antipsychotics, although data is limited. No one drug has been found to be safer in terms of CVAE risk. A higher dose, older age, vascular dementia and comorbid atrial fibrillation have been noted as risk factors for the development of CVAEs in this population group. It appears that the time frame for which the risk of CVAEs remains elevated is about 20 months.<sup>262</sup>

#### *4.8.3.2 All-cause mortality risk*

The year following the U.K. cerebrovascular safety warning, the U.S. Federal Drug Administration (FDA) performed an analysis of 17 Randomised Controlled Trials (RCTs) of atypical antipsychotics in patients with dementia which resulted in a black box warning for significant increase in mortality risk (OR 1.7).<sup>64,257,268</sup> The causes of death were varied with the most common being heart-related deaths (e.g. heart failure and sudden death) or pneumonia.<sup>64</sup>

A subsequent independent review of 15 RCTs by Schneider *et al.* evaluated a total of 3 353 patients randomised to atypical antipsychotic drugs and 1 757 patients randomised to placebo. Death occurred more often among patients randomised to drug treatment: 118 (3.5%) versus 40 (2.3%). The OR by meta-analysis was 1.54, (95% CI 1.06-2.23;  $p=0.02$ ) and, went further to state there was no difference in mortality rates among the different atypical antipsychotics.<sup>112,261</sup>

Several years later, the U.S. black box warnings were extended to include typical antipsychotics in light of retrospective cohort studies such as Wang *et al.*'s study of over 22 890 older patients, which reported a higher mortality risk (around 37%) amongst users of typical antipsychotics compared to atypical antipsychotics.<sup>64,127</sup> Significantly, the mortality risk was shown to increase with higher doses of either type of antipsychotic.<sup>214</sup> Although some reviewers note there were methodological limitations to this study, it is now generally accepted that the risk of death appears to be at least as high for typical antipsychotics.<sup>259,269</sup>

There is recent evidence that the mortality risk associated with antipsychotics progressively increases over time.<sup>259,266</sup> DART-AD (Dementia Antipsychotic withdrawal Trial- Alzheimer's Disease) was an antipsychotic withdrawal trial which involved 105 dementia patients in British RACFs treated with risperidone, typical antipsychotics or placebo. Half the sample continued antipsychotic treatment and the remaining patients were given placebo.<sup>270</sup> When these patients were monitored over 36 months the 12-month survival rate was 70% in the treatment group vs. 77% placebo; 46% vs. 71% at 24 months, and 30% vs. 59% at 36 months, strongly implying that the mortality increases with duration of antipsychotic use.<sup>266</sup>

In Mittal *et al's* comprehensive recent literature review of the risk of CVAEs and death in patients with dementia treated with antipsychotics 14 studies which addressed the risk of mortality were included.<sup>262</sup> They concluded that the mortality risk is about 1.2 to 1.6 times higher for patients with dementia taking either atypical or typical antipsychotics. Again, no drug was found to be safer than another in terms of mortality rates. Older age, higher dose, male gender, severe dementia, and functional impairment were associated with a higher risk of death. The mortality risk remains elevated possibly to 2 years, although more long-term studies are needed.<sup>262</sup>

The cause of the increased mortality risk associated with antipsychotics is unknown although several researchers have speculated that sedation resulting from treatment may lead to a reduction in activity level resulting in increased vulnerability to chest infections and aspiration.<sup>261</sup> Other proposed mechanisms involve metabolic derangements, pulmonary and thrombotic embolism, EPS affecting respiratory function and cardiac events due to prolongation of the QT interval.<sup>109,125</sup>

#### **4.8.4 Guidelines for the use of antipsychotics for BPSD**

In light of the doubtful risk/benefit ratio of antipsychotics, various organisations have released guidelines/recommendations on the use of these agents.<sup>64,94,109,244,246,259</sup> The most recent guidance in relation to Australian practice was published by the Royal Australian & New Zealand College of Psychiatrists in 2009 shortly after the U.S. and European safety warnings.<sup>94</sup> Table 17 provides a summary of this practice guideline:

**Table 17: Summary of RANZCP Practice Guideline: Antipsychotic medications as a treatment of behavioural and psychological symptoms in dementia<sup>94</sup>**

1.	A comprehensive assessment of the patient's physical health and disability, psychiatric condition, cognitive performance and social circumstances should precede a management plan.
2.	The clinician should target specific symptoms that are of concern in the patient. Mental disorders co-morbid with dementia such as major depression requires specific appropriate pharmacotherapy.
3.	The choice of which antipsychotic to use is a clinical one based on a careful risk-benefit analysis for each patient.
4.	Monitoring at baseline and then on a 2-4 weekly basis will assist in the clinical assessment of antipsychotic effectiveness and offer guidance in any necessary dosage adjustments.
5.	It is important that the need for ongoing treatment is reviewed on a regular basis (such as three monthly) and, where appropriate, attempts are made to withdraw the medication.
6.	Informed consent is essential. Information about the risks involved in prescribing medication is conveyed to the person or body giving consent.

The RANZCP Guidelines recommend that antipsychotic medication should be used with caution in older people to manage BPSD. However, these guidelines fail to emphasise the importance of evaluation of potential causes or contributors to behavioural symptoms and do not endorse the first-line use of non-pharmacological interventions.<sup>94 96,109,198,244</sup> In contrast to international and national guidelines (Australian Medicines Handbook Drug Choice Companion: Aged Care, Therapeutics Guidelines Psychotropic and NSW Health), there is an absence of a clear statement that antipsychotics should be prescribed at the lowest effective dose for the shortest period of time when used to treat BPSD. However, it should be acknowledged that all the Australian professional guidelines state that treatment should be monitored, reviewed every 3-6 months, with withdrawal attempts conducted regularly.<sup>164,165,170,242,271,272</sup>

#### **4.9 Other medications used to manage BPSD**

The efficacy and safety of pharmacological alternatives to antipsychotics to treat BPSD is largely unknown.<sup>253</sup> The *cholinesterase inhibitors* (donepezil, galantamine and rivastigmine) block acetylcholinesterase, thus increasing CNS levels of acetylcholine which potentially improves cognition in dementia.<sup>273</sup> This class of drugs has also been associated with a small positive effect on the NPI, a behavioural outcome measure (see Appendix A).<sup>273</sup> A recent meta-analysis examined 14 RCTs of cholinesterase inhibitors for effectiveness to treat BPSD with the median study length of 24 weeks. The reviewers stress that much of the data on behaviour is obtained from secondary outcome measures and post-hoc analyses of patients with mild behavioural symptoms, thus limiting conclusions about efficacy for more severe behaviour.<sup>109,197</sup> The conclusion of the meta-analysis was that: '*cholinesterase inhibitors appear to have, at best, a modest impact on neuropsychiatric symptoms in Alzheimer's*

disease'.<sup>181</sup> Some experts propose that cholinesterase inhibitors are more effective at treating symptoms of depression/anxiety than agitation/aggression and have suggested that the use of cholinesterase inhibitors may defer BPSD emergence and could possibly facilitate the use of lower doses of psychotropic agents to control behaviour.<sup>260,261</sup> Common side effects of cholinesterase inhibitors are linked to cholinergic excess and include nausea and vomiting, bradycardia, muscle cramps, insomnia and increased dyspepsia.<sup>64</sup>

*Memantine*, another 'cognition enhancing' agent, works by partially blocking the N-methyl-D-aspartic acid receptor thus preventing excess stimulation of the glutamate system, which influences memory.<sup>273</sup> Memantine is indicated for moderate to severe Alzheimer's disease.<sup>260</sup> An analysis of pooled data from 6 RCTs found a small, but significant, difference in the NPI at 12 weeks and 24/28 weeks in those patients taking memantine, compared to those taking placebo.<sup>261</sup> However, like cholinesterase inhibitors, data regarding behavioural effects comes from secondary outcome measures and post-hoc analyses.<sup>112</sup> Furthermore, there is doubt over whether the small difference observed in behavioural measures with both cholinesterase inhibitors and memantine translates to a clinically meaningful outcome.<sup>273</sup> Reported adverse effects are infrequent and mild, including dizziness, headache, agitation, falls and constipation.<sup>64</sup> *Antidepressants* have also been used to treat agitation; however, evidence for effectiveness is mixed, with some studies showing benefit and others showing no benefit.<sup>182</sup> The antidepressants with the best evidence for efficacy are the selective serotonin reuptake inhibitors (SSRIs).<sup>274</sup> In a recent trial, 103 non-depressed dementia patients hospitalised due to behavioural symptoms were randomised to either citalopram or risperidone for 12 weeks.<sup>275</sup> Agitation and psychosis decreased in both groups, there were no significant differences in effectiveness between the two treatments yet there were significantly more adverse effects reported in the risperidone group.<sup>274,275</sup> Reviewers of this particular trial have commented that the study was too underpowered to make firm conclusions, especially factoring the high drop-out rate. They also concluded that the absence of differences between antipsychotic and antidepressants may reflect a similar lack of efficacy, rather than equivalent effectiveness.<sup>260,275</sup> Antidepressants are also associated with adverse effects. SSRIs can produce nausea and vomiting, hyponatraemia, falls, agitation and movement disorders.<sup>64</sup> Tri-cyclic antidepressants (TCAs) are not recommended in people with dementia, due to their prominent anticholinergic effects.<sup>64</sup>

Given their 'mood stabilising' properties, *anticonvulsants* have also been evaluated for effectiveness to treat dementia-related agitation. A Cochrane review examined three RCTs of sodium valproate, concluding that low doses were not effective to manage agitation but that high doses were associated with unacceptable adverse effects.<sup>276</sup> In contrast, there is preliminary evidence that carbamazepine has modest efficacy for agitation in dementia, with a small 6-week RCT of carbamazepine demonstrating benefits over placebo.<sup>261,277</sup> However, the long-term use of carbamazepine in older people is not recommended due to the risk of bone marrow

suppression, high rate of drug-drug interactions and a recent safety warning on the emergence of depressive symptoms with treatment.<sup>182,246</sup>

Finally, *benzodiazepines* are often used to manage behavioural symptoms associated with dementia, despite limited trial data appraising effectiveness.<sup>278</sup> Of the studies that have trialled benzodiazepines, most were found to have serious methodological concerns and there is no data concerning long-term efficacy.<sup>64,197</sup> An 8-week RCT compared haloperidol, oxazepam and diphenhydramine for the short-term management of agitated behaviour in severely demented patients, reporting that all three drugs had an equivalent effect.<sup>182,279</sup> Aside from the limited evidence for effect aspect, benzodiazepines are not recommended for routine use in people with dementia.<sup>64</sup> Not only are they strongly associated with tolerance and dependence but they are also linked with significant adverse effects, including excessive sedation, confusion, falls and paradoxical increase of agitation in dementia.<sup>197,246</sup>

Although the safety of alternative treatments for BPSD is ill-defined there is some evidence that antidepressants, anticonvulsants and benzodiazepines do not carry the same mortality risk of antipsychotics.<sup>261</sup> A large retrospective cohort study compared the 12-month mortality rates of antipsychotics with antidepressants, anxiolytic/hypnotics and anticonvulsants, reporting that the mortality risks were significantly lower for the alternate psychotropic medication classes.<sup>280</sup>

In regards to other treatment options for BPSD aside from antipsychotics, the two main Australian practice-based guidelines; the Therapeutic Guidelines - Psychotropic and the AMH Drug Choice Companion: Aged Care both endorse the use of antidepressant medication only when depressive symptoms are present and emphasize that benzodiazepines should be used on a short-term basis for BPSD when other treatments have failed.<sup>119,272</sup> The AMH Drug Choice Companion: Aged care reference suggests that anticonvulsant treatment only be considered if other treatments prove ineffective.<sup>119,272</sup> The International Psychogeriatric Association (IPA) has produced a summary of guidelines (Table 18) for the pharmacological management of BPSD which concurs closely with clinical trial evidence and the current Australian Guidelines.<sup>93,119,272</sup>

**Table 18: IPA Guidelines<sup>93</sup>**

Guidelines for Use of Pharmacological Agents in BPSD	
Agent	Application (page reference for details)
Any agent	<p>Patients with dementia and elderly are often hyper-responsive and/or show less predictable effects of pharmacotherapy. Therefore:</p> <ul style="list-style-type: none"> <li>• Always initiate treatment with 1/3 to 1/2 of the usual adult dose</li> <li>• Review frequently, titrate for desired and adverse effects</li> <li>• If results are sub-optimal, be prepared to switch to a different agent or class of agents</li> </ul>
Antipsychotics: Typical Atypical	<p>Psychotic symptoms—e.g., delusions, hallucinations, paranoia</p> <p>Agitated</p> <p>Aggressive</p>
Antidepressants SSRIs, SNRIs, avoid anticholinergic TCAs	<p>Depressive / depressed</p> <p>Anxious (Antidepressants with anxiolytic effects)</p> <p>Agitation, moderate / severe psychotic symptoms</p>
Cholinesterase inhibitors	<p>Cognitive deficits</p> <p>Variable findings, but possibly useful in some BPSD</p>
Benzodiazepines	<p>Premedication for anxiety-inducing events; sleep / wake problems</p> <p>Significant adverse effects; Long-term use discouraged</p>
Mood stabilizers Anticonvulsants	<p>Limited evidence of efficacy in BPSD and adverse effects recommend against use outside specialist care</p>
Other drugs	<p>Buspirone: limited data, not available in Europe</p> <p>Gabapentin: limited data, possible use in anxiety, agitation</p> <p>Beta-blockers: limited data, not recommended outside specialist units</p> <p>Hormones: Not recommended outside specialist units</p> <p>Antihistamines: contra-indicated</p>

## CHAPTER FIVE: MANAGEMENT OF ANXIETY

### 5.1 Anxiety

Anxiety disorders have historically been considered a problem of childhood and early adulthood, yet anxiety surpasses all the other mental health conditions in its prevalence among older adults (estimated to occur in 10-20% of people over 65 years), being twice as common than dementia (8%) and 4-8 times more prevalent than major depression (1-3%).<sup>20</sup> Anxiety is even more common in patients with early dementia (38%) and in Parkinson's disease (38%).<sup>20</sup> Many of these prevalence rates, though, are likely to be underestimated, given the tendency of older adults to underreport or deny psychological symptoms and difficulty with diagnosis.<sup>21</sup> It is highly likely then that a significant proportion of RACF residents will have symptoms of anxiety.

Anxiety involves feelings of apprehension and fear, and is often accompanied by physical symptoms such as heart palpitations and sweating.<sup>281</sup> Unlike the mild, brief anxiety caused by a stressful event, 'anxiety disorders' are chronic and often grow progressively worse if not treated.<sup>282</sup> Anxiety disorders interfere with sleep, daily functioning and cause considerable distress.<sup>282,283</sup> Far from being benign, anxiety disorders in older people are associated with increased risk of cardiovascular disease, asthma, cancer, and contribute to cognitive and memory impairment.<sup>283,284</sup>

#### 5.1.1 Diagnosis of late-life anxiety

Despite their high prevalence and significant impact, anxiety disorders are often unrecognised and undertreated in older adults. Late-life anxiety can often be missed as older adults for reasons outlined above and there is often substantial symptom overlap with other conditions, including depression (e.g. sleep disturbance, concentration and agitation) and medical illnesses (e.g. chest and abdominal pain, and shortness of breath).<sup>21,282</sup> Diagnosis is based on a thorough history gained from the patient and the patient's caregivers, mental state examination, physical examination and laboratory tests used to screen for physical factors that could be contributing to the anxiety.<sup>285</sup> It is important to identify any medications which may be exacerbating symptoms and also minimise the use of anxiogenic substances, such as caffeine.<sup>14</sup>

Although there are several scales that can be used to screen for anxiety disorders, there is still considerable debate over diagnostic criteria and the most appropriate test to use.<sup>286,287</sup> The main limitation is that many of the available instruments are poor at detecting anxiety in older people. In addition, many standard anxiety screening tools cannot be used in patients with cognitive impairment.<sup>287</sup> A new anxiety scale, the 20 question 'Geriatric Anxiety Inventory'

(GAI) has recently been developed to overcome these limitations (Figure 9).<sup>287</sup> Each positive response is allocated a point, with a score over 10 indicating a anxiety Disorder.<sup>287</sup>

**Figure 9: The Geriatric Anxiety Inventory (GAI)<sup>287</sup>**

- |   |  |
|---|--|
| 1. I worry a lot of the time                          | 11. My own thoughts often make me anxious          |
| 2. I find it difficult to make a decision             | 12. I get an upset stomach due to worrying         |
| 3. I often feel jumpy                                 | 13. I think of myself as a nervous person          |
| 4. I find it hard to relax                            | 14. I always anticipate the worst will happen      |
| 5. I often cannot enjoy things because of my worries  | 15. I often feel shaky inside                      |
| 6. Little things bother me a lot                      | 16. I think that my worries interfere with my life |
| 7. I often feel like I have butterflies in my stomach | 17. My worries sometimes overwhelm me              |
| 8. I think of myself as a worrier                     | 18. I sometimes feel a great knot in my stomach    |
| 9. I can't help worrying about even trivial things    | 19. I miss out on things because I worry too much  |
| 10. I often feel nervous                              | 20. I often feel upset                             |

### **5.1.2 Subtypes of anxiety disorders**

There are five to six different subtypes of anxiety disorders. As treatments for the different types vary, one of the main aims of assessment is to identify the predominant type of anxiety the patient is suffering from.<sup>119</sup> A list of core features and suggested screening questions for each of the DSM-IV-TR anxiety disorders is provided in Table 19.<sup>282,288,289</sup> It is, however, thought that 90% of presentations of late-life anxiety are accounted for by either Generalised Anxiety Disorder (GAD) or phobia.<sup>284,285,290</sup>

Generalised Anxiety Disorder (GAD) is characterised by persistent anxious mood accompanied by motor tension and autonomic symptoms, for at least six months.<sup>282,291</sup> GAD in late life is a fairly even mix of chronic illness from earlier in life and cases starting for the first time in old age.<sup>285</sup>

Phobia disorders are defined as the persistent and irrational fear of an object, activity or situation resulting in the compelling desire to avoid the phobic stimulus.<sup>291</sup> Among older people, agoraphobia (fear about being in situations and/or places and having an anxiety attack)<sup>64</sup> is the most common.<sup>282</sup> While many of these disorders are of a chronic duration, a significant proportion of phobias in old age are of late onset, often in response to a traumatic event such as a fall.<sup>291</sup>



**Table 19. Types and core features of Anxiety Disorders and useful screening questions (adapted from<sup>282,288,289</sup>)**

Disorder	Symptom Summary	Useful Screening Questions
Generalised anxiety disorder	Diffuse constant anxiety and worry for > 6 months	Are you a worrier? Do you worry about the 'what ifs' in life? Is it hard to stop the worrying? Does worrying keep you from falling asleep? Does your worry ever cause headaches, body aches, or tension?
Agoraphobia	Fear of being trapped in a place <u>and</u> experiencing anxiety	Are you afraid of being alone and unable to get help? Do you avoid doing such things as leaving your home because of this fear?
Social anxiety disorder	Fear of social embarrassment	Do you worry in social situations that people will judge you negatively? Do you avoid social situations because of this fear?
Specific phobia	Fear of specific object or situation	Do you fear anything specifically, such as animals, storms or heights? Do you avoid being in situations where you might encounter this?
Panic disorder	Episodic and overwhelming anxiety	Do you have sudden, overwhelming body anxiety, with shortness of breath, sweating, or tightness in your chest for several minutes?
Post traumatic stress disorder	Traumatic event re-experienced	Do you have anxiety related to a trauma, causing you to have nightmares or flashbacks?

### **5.1.3 The relationship between anxiety and depression in old age**

Is there a link between anxiety and depression? This question has been the subject of much debate. It is well established that the two mental health conditions often occur together. In fact, evidence suggests that up to 50% of older adults with depression have an anxiety disorder, whereas up to 30% of older adults with anxiety disorders have depression.<sup>292</sup> When a random sample of 2640 people over 65 years were tested with the geriatric mental state examination in the 'Medical Research Council Cognitive Function & Ageing Study', over 8% had overlapping symptoms of anxiety and depression. In contrast, pure disorders of anxiety were rare, occurring in less than 1% of the sample.<sup>293</sup> Some researchers are now suggesting that there is little distinction between the two disorders in older people and that anxiety is actually a symptom of depression.<sup>293</sup> Furthermore, as anxiety is more likely to present before a depressive episode, some experts now propose that the effective treatment of anxiety '*can be viewed as a secondary prevention effort to reduce the incidence of late-life depression*'.<sup>292</sup>

## **5.2 The treatment of anxiety disorders**

Limited RCT evidence exists on which to base recommendations for the optimum treatment of anxiety in older people. The first step in the management of anxiety in all age groups is careful assessment, in particular screening for potential causes or contributors of anxiety symptoms.<sup>136</sup> The management of co-morbid physical and psychiatric disorders, medication review, environmental modification and pain management strategies may all alleviate anxiety states.<sup>136,294</sup> Anxiety in people with dementia poses particular challenges as various factors may contribute to the expression of anxiety symptoms, including undiagnosed pain, reactions to medications, as well as environmental and social factors.<sup>136</sup> It is essential to note that anxiety disorders tend to be chronic or recurrent, follow a fluctuating course and treatments are often only partially successful.<sup>271,294</sup> Generally, effect sizes for treatments are in the moderate range with the placebo response regularly exceeding 30%.<sup>294,295</sup>

### **5.2.1 Non-pharmacological treatment of anxiety**

When a patient is diagnosed with anxiety, non-drug treatment should be trialled first, ranging from education aiming to assist patients to understand that their anxiety is manageable, to other measures, including increased social contact, relaxation techniques and formal psychosocial interventions such as cognitive behavioural therapy (CBT).<sup>135,136</sup> CBT used to treat GAD typically includes anxiety education, patients self-monitoring their worrying, evaluating and remodelling predictive worries, relaxation training and rehearsal of coping skills.<sup>135,292</sup>

A Cochrane review of psychological treatments for GAD included 25 studies with a total of 1305 participants.<sup>296</sup> People treated with CBT were more likely to have reduced anxiety than people who received treatment as usual.<sup>296</sup> Interestingly, it was noted that people over 65 years were more likely to drop out of therapy than other age groups.<sup>296</sup> Another review of treatment for late-life anxiety incorporating 17 studies concluded psychosocial interventions were less effective in older people than they are for younger people.<sup>292</sup> There are several explanations to account for this. To start, none of the studies with older people considered long-term outcomes, potentially not allowing adequate time for CBT to impact fully. Further, many of the therapies were delivered in groups, which may be less acceptable to this age group.<sup>292,296</sup> Finally, impaired cognition in many older people may make it difficult for patients to remember many of the skills taught in CBT.<sup>297</sup>

Drug treatment is generally not indicated to treat specific phobias.<sup>294</sup> Instead, graduated exposure to the feared stimulus is first-line treatment. Confronting stimulus and staying until the anxiety diminishes usually leads to the reduction of the fear response. CBT for phobias usually includes addressing distorted risk assessments and feelings of being over-whelmed and recognising the demoralisation that accompanies chronic avoidance.<sup>294</sup>

### **5.2.2 Pharmacological treatment of anxiety**

The pharmacological treatment of anxiety is indicated when anxiety is severe and persistent or if psychosocial interventions alone have been ineffective.<sup>136</sup> Anxiety disorders appear to be caused by a number of inter-related factors, including genetic vulnerability, which interact with certain situations, stress or trauma to produce both ‘psychic’ (e.g. fear and apprehension) and ‘somatic’ symptoms (e.g. palpitations and sweating).<sup>298</sup> There are several major CNS neurotransmitters involved with both types of symptoms, namely noradrenaline, serotonin, dopamine and GABA, which helps explain why a wide range of medications with differing pharmacological properties can be effective to treat anxiety.<sup>295,298</sup>

#### *5.2.2.1 Antidepressant therapy*

Antidepressants are the drug treatment of choice for many anxiety disorders as they are effective anxiolytics but are not associated with dependence.<sup>285,289</sup> Antidepressants are also theorised to be more effective to treat the ‘psychic’ symptoms of anxiety than benzodiazepines, which primarily relieve the ‘somatic’ symptoms.<sup>299</sup> In addition, the use of antidepressant medication will also treat the depression that often coexists with GAD.<sup>300</sup>

In older people suffering from depression presenting with a high level of anxiety, there is no consistent evidence that one class of antidepressant medication is better than another.<sup>285</sup> The selection of an antidepressant is guided by the same principles that apply to the treatment of non-anxious depression. It is important, though, to be aware that a high level of anxiety may delay the response of depression to antidepressant medication.<sup>301</sup>

Numerous RCTs have shown that anxiety in the absence of major depression is also responsive to antidepressant medication.<sup>301</sup> A well-defined mechanism of action for antidepressants in the treatment of anxiety has not been determined, but is theorised to involve the down-regulation of noradrenergic receptors.<sup>135</sup> Data from studies of older patients support the use of the SSRIs (escitalopram, citalopram and setraline) and the serotonin-noradrenaline reuptake inhibitors (SNRIs) ( venlafaxine and duloxetine) for the treatment of GAD in later life.<sup>289,301</sup> As an example, when escitalopram (10-20mg/day), or placebo, was administered to 177 older adults with GAD in a 12-week RCT, improvements in anxiety symptoms were found in 69% of the treatment group, as opposed to 51% of the placebo group.<sup>302</sup> The high placebo response rate reported in this trial is similar to placebo rates found in trials of anxiolytic agents in younger people.

The time taken for older patients with anxiety to respond to antidepressant medication is typically much longer than that for depression, which results in a period of some months before significant clinical improvement is seen.<sup>295,301</sup> Guidelines recommend efficacy be assessed after at least 12 weeks therapy as opposed to 6-8 weeks for depression.<sup>288,289</sup> As antidepressants may

be associated with an initial worsening of anxiety symptoms in some patients it is important to titrate the dose slowly, with regular follow-up and reassurance, for success.<sup>282,288</sup> Several trials have shown that when antidepressant treatment is ceased, about 20-40% of GAD patients will relapse within 6-12 months, suggesting that long term treatment is often required. For this reason the majority of guidelines recommend that therapy should be continued for at least 12 months, with a proportion of patients requiring life-long therapy.<sup>285,299</sup>

The evidence supporting the use of combined therapy (i.e. an antidepressant combined with psychological strategies) is mixed. Although some researchers suggest that optimal outcomes are achieved by combining the two treatment modalities, there is no RCT evidence that combination therapies are more effective than either therapy by itself.<sup>133</sup>

#### *5.2.2.2 Benzodiazepines*

Benzodiazepines are the most frequently prescribed medication for anxiety disorders in older adults.<sup>301</sup> In spite of the promotion of antidepressants for anxiety by both regulatory and professional bodies, the use of benzodiazepines remains high. In a recent study analysing usage patterns of benzodiazepines in Australia, anxiolytic benzodiazepine utilisation actually increased between 2003 and 2007, with the highest rate of use reported in people over 80 years of age.<sup>61</sup>

A recent meta-analysis of GAD treatments conducted by the U.K's National Institute for Clinical Excellence (NICE) reported that the evidence base for benzodiazepines to treat anxiety was much smaller than that for antidepressants. Although there are many studies evaluating benzodiazepines, only 4 RCTs met NICE criteria, and only small to moderate benefits in mean anxiety rating scores were found in these 4 trials.<sup>295</sup> Another meta-analysis comparing various anxiolytic agents reported effect sizes for benzodiazepines that were equal to those of SSRIs.<sup>303</sup> Of all treatments, the highest effect size was recorded for venlafaxine (0.45), followed by benzodiazepines (0.38) and SSRIs (0.36).<sup>303</sup> It is significant that there were no RCTs evaluating long-term benzodiazepine use in either meta-analysis (> 16 weeks).<sup>137,303</sup>

Recent data is emerging that benzodiazepines may not be as effective anxiolytics as originally thought.<sup>304</sup> When Martin *et.al.* examined all available double-blind RCTs evaluating benzodiazepines in the treatment of GAD, their primary outcome was withdrawal for any reason. Of over 1000 studies, only 23 RCTs met study criteria, with the majority of trials conducted for less than 4 weeks.<sup>305</sup> The meta-analysis found that the rate of withdrawal showed no clear advantage for benzodiazepines when compared to placebo. However, the relative risk for dropouts because of adverse effects was 1.54, an additional risk of 50% for benzodiazepines over placebo.<sup>305</sup> Another recent study assessed the effect of diazepam in mice exposed to a three-dimensional maze. This study found that diazepam did not reduce anxiety in the mice. As

doses were increased, the mice simply became more sedated, rather than less anxious. The authors concluded that this finding suggested that the primary effect of benzodiazepines was sedative, meaning that benzodiazepines may actually mask anxiety symptoms instead of reducing them.<sup>306,307</sup>

Finally, the effects of benzodiazepines on anxiety do not appear to be long-lasting. Evidence suggests that the anxiolytic effects may not be significantly different from placebo after 4-6 weeks of treatment.<sup>299,308,309</sup> One study that strongly indicates that benzodiazepines may not be effective anxiolytics in the long-term comes from France where benzodiazepines are prescribed at a high rate compared to other western countries.<sup>310</sup> When a large sample of 4 257 patients taking benzodiazepines for 6 months or more were assessed for anxiety and depression using standardised clinical scales, 74% of the sample still had significant anxiety symptoms impairing their overall function, with 60% of the sample having symptoms of major depression according to the DSM-IV TR. The French researchers commented that this study provided evidence of the lack of efficacy of benzodiazepines, despite long term treatment.<sup>310</sup>

#### *5.2.2.3 Other drug treatment options for anxiety*

Other medication options for late-life anxiety disorders include buspirone (for GAD only), and there is limited evidence of the effectiveness of anticonvulsants and antipsychotics.<sup>130,289</sup> Buspirone, a partial agonist of serotonin 5-HT<sub>1A</sub> receptors, has been found to be as effective as benzodiazepines without their dependence.<sup>130</sup> Like antidepressants, buspirone has a delayed onset, taking a few weeks to show clinical effect, but has diminished efficacy in persons who have previously been treated with benzodiazepines.<sup>130</sup> For this reason, its usefulness in the management of older patients with GAD, many of whom have been treated with benzodiazepines, is unclear.

### **5.3 Guidelines for the use of benzodiazepines in the treatment of anxiety**

Benzodiazepines do not appear to be effective anxiolytics in the long-term. Not only are they associated with cognitive and functional impairment, falls, and paradoxical inhibition, but many people become dependent on benzodiazepines, developing tolerance that requires dose increase for effect.<sup>133,311</sup> It should be noted that although these agents have been over-used as primary treatment for anxiety in older adults, they do have a role in certain situations.<sup>301</sup>

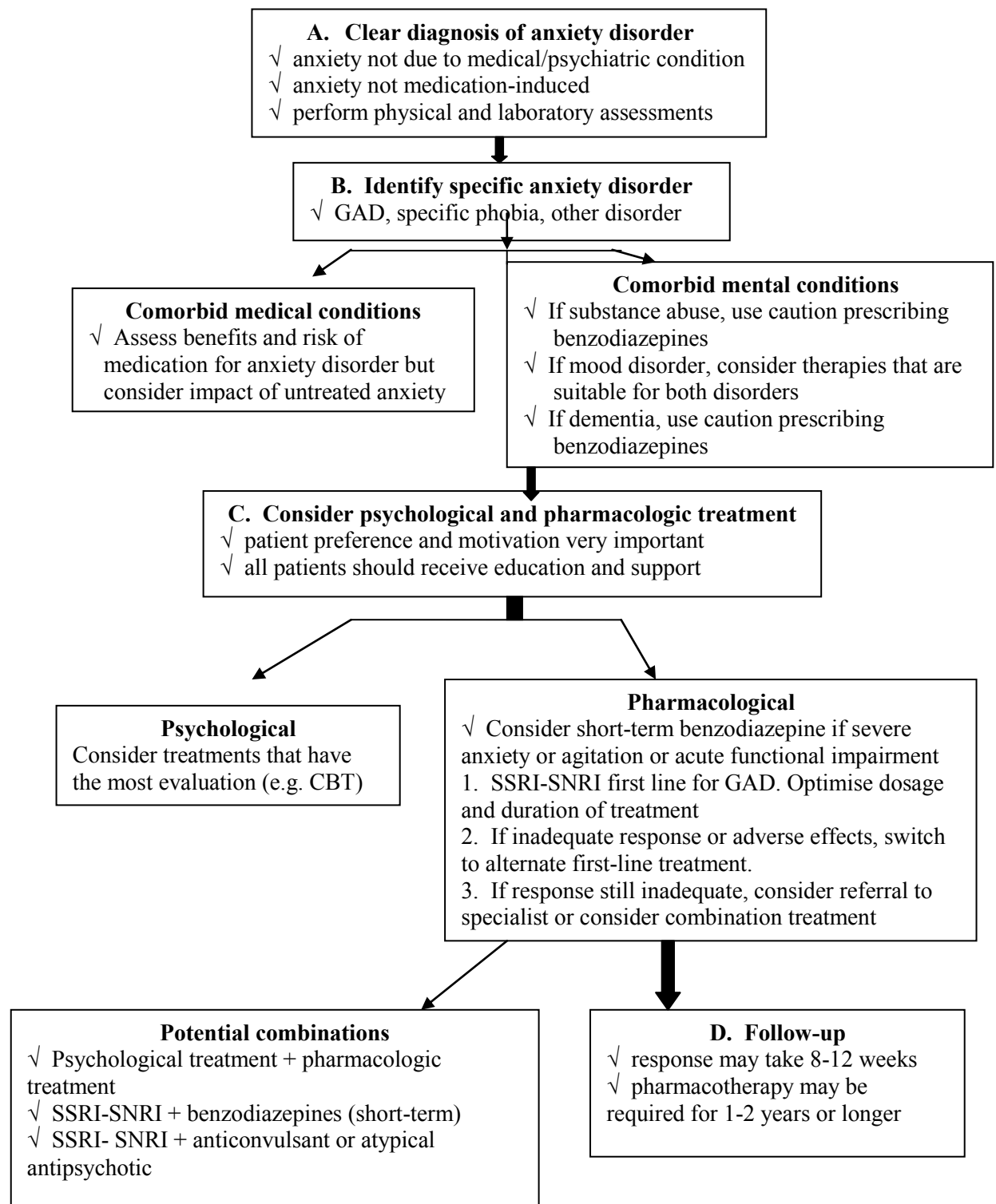
One advantage of the benzodiazepine class over antidepressants is their rapid onset of effect. Many clinicians advocate prescribing benzodiazepines for anxiety on a short-term basis when an antidepressant agent is initiated. Not only does this combination therapy have the benefit of providing initial symptom relief, but some of the initial side effects associated with antidepressants (e.g. agitation and insomnia) may be eased.<sup>130</sup> Once patients have an adequate

duration of antidepressant treatment, professional guidelines recommend that the benzodiazepine dose should be gradually tapered, with the aim of eventual cessation.<sup>130</sup>

It should also be acknowledged that some older patients with longstanding anxiety who have been maintained on a benzodiazepine for some years may experience a significant worsening of anxiety when attempts are made to withdraw this medication, even when the dose is tapered very gradually. In such cases, if the benzodiazepine is not causing significant adverse effects, it is usually less disruptive to patients to leave them on the medication and monitor them on a regular basis. If adverse effects do become problematic as the person grows older, dose reduction, rather than complete discontinuation, may be the best compromise.<sup>301</sup>

Several algorithms have been developed to guide health professionals in the management of anxiety disorders. One of the most up-to-date and comprehensive algorithms has been developed by the Canadian Psychiatric Association (see Figure 10).<sup>144,146,299</sup> The AMH Drug Choice Companion: Aged Care and the Therapeutic Guideline: Psychotropic guidelines, in line with this algorithm, recommend excluding external causes of anxiety and trialling initial psychological therapy before prescribing antidepressant treatment.<sup>119,272</sup> While benzodiazepines are noted to be effective, the majority of guidelines discourage long-term use and warnings are given in relation to an increased risk of confusion and falls.<sup>119,272</sup> The National Prescribing Service (NPS) has also released several prescribing practice reviews on the treatment of anxiety, with the most recent review released in 2009.<sup>311</sup> In line with current evidence, the key messages are to assess for external causes, treat non-pharmacologically first-line, use antidepressants when appropriate and reserve benzodiazepine use for short periods only.<sup>311</sup> Benzodiazepine use for anxiety should be reserved short-term for people who have not responded to either psychosocial or antidepressant treatment.<sup>301,311</sup> When these medications are used, the minimal effective dose and the shortest possible duration of use should be chosen.<sup>133,144</sup> All patients who are dependent on benzodiazepines should be offered gradual dose reduction every 6-12 months and encouraged to utilise non-drug therapies.<sup>289</sup> These professional guidelines all accord with current research evidence as outlined in the present chapter.

**Figure 10: Clinical practice algorithm: management of anxiety disorders<sup>299</sup>**



## CHAPTER SIX: MANAGEMENT OF SLEEP DISTURBANCE

### 6.1 Sleep disturbance in older people

Disturbances in sleep increase as people age. It has been estimated that over half of people over 65 years in the community and up to two-thirds of people in RACFs experience sleep disorders.<sup>312</sup> In a U.S. survey of over 9000 older adults (> 65 years), 57% of respondents had at least one chronic sleep complaint.<sup>313</sup> However, sleep disturbance is not an inevitable consequence of growing old. There is a strong bi-directional relationship between ill health and sleep disturbance. Studies have shown that older people with a chronic medical condition (e.g. hypertension, osteoarthritis and depression) are at higher risk for sleep disturbance.<sup>314</sup> On the other hand, older people with sleep disturbance are at higher risk of developing these types of chronic medical conditions.<sup>315</sup>

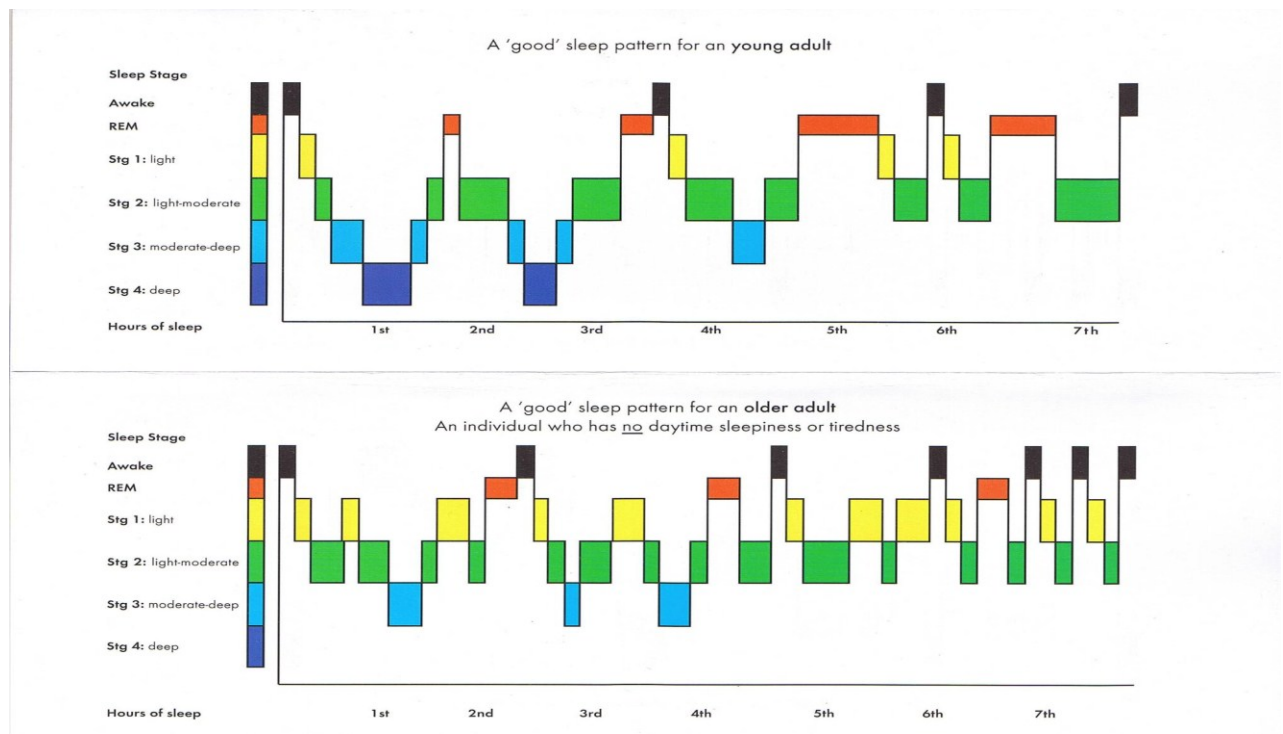
Although often dismissed as a minor complaint, sleep disturbance in older people is actually associated with significant morbidity.<sup>314,315</sup> In addition to daytime dysfunction, older adults with difficulty sleeping report poorer quality of life and more symptoms of anxiety and depression.<sup>315</sup> Cognitive decline, admission into RACFs and greater health care utilisation are linked to sleep disorders.<sup>314,315</sup> Sleep disorders are also strongly related to falls in older adults, with factors such as sleeping less than 7 hrs/night and day-time napping associated with a greater falls risk.<sup>316</sup> When the relationship between insomnia and falls in older people was examined in 34 163 residents of 437 American RACFs, untreated insomnia was associated with a 52% greater risk for falls.<sup>317</sup>

#### 6.1.1 Sleep changes and ageing

There is a common belief that the amount of sleep needed per night decreases with age. Yet in a large survey of older adults, the total amount of sleep reported was 7 hours a day, the same or more than that reported by younger adults.<sup>318</sup> However, major changes do occur to the daily sleep-wake cycle as people age.<sup>315</sup> The normal sleep-wake process is the result of a complex interaction between two 'drives', the homeostatic sleep drive and the circadian wakefulness drive.<sup>315</sup> A wide variety of physiological, psychological and environmental factors can influence this process.<sup>315</sup> Sleep is not one long period of unconsciousness but a series of cycles each lasting approximately 90 minutes.<sup>319</sup> Each cycle consists of Rapid Eye Movement (REM) and non-REM (NREM) states. NREM can be further broken down into: Stage 1, light sleep; Stage 2, light-moderate sleep (most prevalent stage); Stage 3, moderate-deep sleep, and Stage 4, deep sleep (See Figure 11).



**Figure 11: Sleep cycles for younger and older adults<sup>301</sup>**



The contrasting sleep cycles between the younger and older adults shown in Figure 11 show that:

- The younger adult spends longer periods in stage 2 sleep, gains more stage 3 and 4 sleep and wakes less frequently; and,
- The older adult spends a greater proportion of the night in lighter stage 1 and 2 sleep from which they can be easily aroused, wakes four to five times a night, and generally does not reach a stage 4 deep sleep.<sup>319,320</sup>

A large meta-analysis of 65 sleep studies representing 3577 participants found that the amount of slow wave sleep (stages 3 and 4) decreases by 2% per decade in young and middle-aged adults but after age 60, remains constant.<sup>321</sup> This altered sleep-wake pattern in older adults means they are prone to sleep fragmentation, they frequently feel un-rested and are inclined to nap during the day.<sup>315</sup>

With advancing age, changes occur in circadian rhythm patterns influencing core body temperature, hormone secretion and the sleep-wake cycle.<sup>322</sup> Circadian rhythms are usually regulated by a specific area in the brain called the 'suprachiasmatic nucleus' (SCN).<sup>322</sup> The SCN is a group of neurons located at the base of the hypothalamus, just above where the optic nerves meet, and is influenced by exogenous stimuli; the most significant of which is light.<sup>323</sup> It is hypothesized that the SCN deteriorates as people age and therefore functions less effectively.<sup>322</sup>

Other age-related changes may affect circadian rhythms. Endogenous melatonin, secreted by the pineal gland, is an essential component in sleep, with its production highest during the

night when light stimuli is minimal.<sup>324</sup> Melatonin secretion gradually decreases with age, potentially contributing to circadian rhythm disturbance.<sup>323</sup> In addition, a phase advance occurs in the circadian rhythm in many older people, meaning that they become tired earlier in the evening and wake up earlier.<sup>312</sup>

Sleep in people with dementia is marked by an increased duration and frequency of awakenings and increased day time napping, which appear to be an exacerbation of sleep changes found with 'normal ageing'.<sup>312,324,325</sup> A direct association may exist between dementia and circadian rhythm disturbance as people with more advanced dementia have greater circadian rhythm alterations.<sup>326</sup> Damage to the SCN and the neuronal pathways that initiate and maintain sleep are thought to be contributing factors.<sup>327</sup>

### **6.1.2 Sleep disorders**

It is generally acknowledged that ageing *per se* does not cause sleep disorders. The majority of sleep disorders are related to medical and psychiatric conditions associated with ageing.<sup>312</sup> There are, however, several specific sleep disorders which directly disrupt sleep. Sleep-disordered breathing (SDB) is one of these and this term covers a spectrum of respiratory events that occur during sleep, ranging from snoring at the milder end of the spectrum to sleep apnoea at the more severe end.<sup>312,323</sup> Sleep apnoea is characterised by repeated episodes of apnoea lasting for at least 10 seconds due to airway closure.<sup>312</sup> Events are considered clinically significant when they occur 15 or more times per hour of sleep.<sup>328</sup> SDB has reported prevalence rates ranging from 20% - 62% (depending on the diagnostic criteria used), with male gender, age and obesity as major risk factors.<sup>312</sup> SDB is generally treated with continuous positive airway pressure. This treatment is not curative but significantly reduces the number of apnoeic episodes.<sup>328</sup>

Two other clinical sleep disorders are 'periodic limb movements'(PLM) and 'restless leg syndrome'(RLS) which are estimated to affect up to 45% of older people.<sup>315</sup> PLM are best described as leg kicking every 20-40 seconds over the course of a night.<sup>312</sup> Each movement may result in an awakening which causes sleep fragmentation and daytime sleepiness.<sup>323</sup> RLS is characterised by the urge to move the legs repeatedly before sleep, resulting in difficulty with sleep initiation.<sup>312</sup> The aetiology underlying both syndromes is unknown.<sup>329</sup> The recommended treatment for PLM and RLS are dopamine agonists.<sup>330</sup>

Another sleep disorder is termed 'REM disorder' and occurs when the muscle paralysis normally found in REM sleep is absent. Patients with this condition 'act out' their dreams, so display movement during REM sleep, including kicking and yelling.<sup>323</sup> This disorder is strongly related to the development of neurological disorders. In one study, 50% of those diagnosed with REM disorder developed Parkinson's disease within 3-4 years.<sup>331</sup> Older people, particularly

men, have a higher incidence of REM sleep disorder.<sup>323</sup> The treatment of choice is clonazepam, but like other long-acting benzodiazepines, use is associated with adverse effects outlined previously.<sup>328</sup>

## **6.2 Insomnia**

Insomnia is defined as a complaint of disturbed sleep in the presence of adequate opportunity and circumstance for sleep.<sup>315</sup> The condition may involve difficulty initiating sleep or maintaining sleep, waking too early or non-restorative sleep.<sup>315</sup> For a diagnosis of insomnia to be made, the sleep problem must have a negative effect on daily function.<sup>332</sup> Insomnia is classified as either primary or comorbid insomnia. According to DSM-IV-TR criteria, 'primary insomnia' is essentially a diagnosis of exclusion, used when the cause of insomnia cannot be identified.<sup>4</sup> In a study of over 6 000 older people, only 10-20% of the sample were diagnosed with primary insomnia.<sup>313</sup> Comorbid insomnia is significantly more common in the older population and is often associated with psychiatric and medical disorders, and sleep disorders such as SDB or RLS.<sup>315</sup>

It is well recognised that the leading causes of co-morbid insomnia are mental health conditions.<sup>314,315</sup> A joint study conducted by the American Psychiatric Association / National Institute of Mental Health reported that 'insomnia related to mental health' was the most frequent sleep diagnosis (46%) among patients with an insomnia complaint referred to five sleep centres; primary insomnia was the next most frequent sleep diagnosis, accounting for 22% of the sample.<sup>333</sup>

Depression and insomnia, in particular, are closely related to each other.<sup>323</sup> It is estimated that about 20% of people with insomnia have depression, and about 90% of people with depression report a sleep disturbance.<sup>334</sup> Like other mental health conditions, insomnia is often a chronic and recurrent condition. Between 50% and 80% of people with insomnia still complain of sleep disturbance after follow-up intervals of 1 to 3.5 years.<sup>335</sup>

Insomnia is strongly related to physiological conditions as well, with studies finding the majority of patients with osteoarthritis, chronic pain and diabetes report insomnia.<sup>285</sup> Other chronic health conditions associated with insomnia include congestive heart failure, nocturia, cancer, respiratory disorders and neurological conditions, including stroke and Parkinson's disease.<sup>315,323</sup>

### **6.2.1 Medications and insomnia**

Chronic health conditions can cause insomnia, yet often the medications used to treat these conditions can also result in, or contribute towards, insomnia.<sup>315</sup> Beta-blockers, bronchodilators, corticosteroids, decongestants, caffeine and diuretics, as well as other cardiovascular,

neurological, psychiatric and gastrointestinal medications may cause or exacerbate insomnia.<sup>315</sup> Moreover, the use of sedating medications during the day hours (e.g. antihistamines, anticholinergics, narcotics and many psychotropic medications) can cause drowsiness which precipitate day-time sleeping, and consequently, results in further disruption of sleep/wake patterns.<sup>323</sup> Changing the timing of administration of a medication can often ameliorate medication-related sleep difficulties.<sup>328</sup> Table 20 summarises key factors which may cause or exacerbate insomnia.<sup>314</sup>

**Table 20: Factors which can cause or contribute to insomnia<sup>314</sup>**

<b>Dietary/Lifestyle</b>	<b>Medications</b>	<b>Psychiatric disorders</b>
Excessive fluid intake	Bupropion	Anxiety
Caffeine	Corticosteroids	Bipolar disorder
Alcohol	Diltiazem	Delirium
Nicotine	Diuretics	Dementia
	Dopamine agonists	Depression
<b>Medical conditions</b>	Methyldopa	Schizophrenia
Cancer	Phenytoin	Substance abuse
Chronic pain	Propranolol	
Diabetes	SSRIs	<b>Situational</b>
GORD	Sibutramine	Life change
Heart failure	Theophylline	Loss of loved one
Menopause	Thyroid	Stress
Multiple sclerosis	Verapamil	
Obesity	Ginseng	
Pulmonary disease	Phenylephedrine	
Urinary incontinence	Pseudoephedrine	

### 6.2.2 Sleep disturbances in RACFs

Although few researchers have measured the prevalence of sleep disturbance in RACFs, many experts suggest that sleep difficulties are more common and more severe in this setting than in the community.<sup>328,336</sup> Haesler *et al.*, in a review of the literature around sleep, estimated that over two thirds of RACF residents have insomnia.<sup>337</sup> The reasons for this high prevalence are multifactorial. To start, medical and psychiatric comorbidities are common, as are neurodegenerative disorders such as dementia and Parkinson's disease, all of which interfere with sleep.<sup>315</sup> In addition, nearly all residents take multiple medications, many of which cause or exacerbate sleep disorders. On average, residents of RACFs take 5-8 different medicines each day and many take more than 10 medicines per day.<sup>323</sup>

Specific sleep disorders are also common in RACFs although there is limited research in RACFs. It is estimated that up to 75% of residents have mild sleep apnoea.<sup>338</sup> RLS may be a possible reason for motor restlessness and wandering among residents with dementia.<sup>328</sup> Finally, as many residents of RACFs have Parkinson's disease the incidence of REM sleep behaviour disorder is likely to be high.<sup>328</sup>

For people residing in the aged care setting, natural changes to circadian rhythms and comorbid insomnia are likely to be exacerbated by both environmental and institutional elements of the RACF itself, with surveys of older residents reporting noise and light disruption, nocturia and pain as the most common causes of sleep disturbance.<sup>339</sup> Exposure to daytime bright light, in particular, is very limited. In a study by Schochat *et al.* the median amount of bright light exposure per day in RACF residents with dementia amounted to just 10 minutes.<sup>340</sup> Conversely, lights are often switched on at night disrupting nocturnal sleep, with one study conducted in 4 RACFs revealing an average of 5 light level changes per night.<sup>341</sup> This study also found that environmental light and noise accounted for 50% of the residents' waking episodes. Sources of noise included staff talking, linen carts and slamming doors.<sup>341</sup> Another study reported that residents were given nursing care at night, delivered with the lights on and normal conversational voice volumes spoken, regardless of whether or not they were asleep.<sup>342</sup>

Structured daytime observations in RACFs have shown that residents often spend extended periods of time in bed, allowing them to doze intermittently throughout the day, with one study reporting that residents spent up to 17 hours per day in bed to achieve only eight hours total sleep time.<sup>315,343</sup> Excessive daytime sleeping, defined as sleeping for 15% or more during the daytime (from 9am to 5pm), is associated with worse quality of life measures, functional impairment and a greater mean level of nursing assistance.<sup>344</sup> This daytime napping behaviour is extensive. In fact, one U.S. observational study of 200 RACF residents concluded that there is '*often not a single hour in a 24 hour period that is spent fully awake or fully asleep*'.<sup>345</sup> It comes as no surprise then that moving into a RACF itself can precipitate sleep disturbances. In a study of 102 residents in 3 RACFs, napping, nocturnal awakening, problems with sleep initiation and hypnotic use all increased in comparison to pre-admission measures.<sup>346</sup>

### **6.3 Management of Insomnia**

The first step in effective management of insomnia is to set reasonable goals and expectations of treatment.<sup>314</sup> The initial assessment of sleep disorders should include a comprehensive medical, psychiatric and sleep history, including a review of all medications.<sup>312</sup> In cases of comorbid insomnia, it is crucial to treat underlying psychological or physiological conditions, if feasible.<sup>314</sup>

The sleep history should ascertain the severity, duration and characteristics of the sleep disorder as well as determining any contributing factors. Night-time symptoms, daytime functioning and napping should all be documented.<sup>347</sup> According to the DSM-IV-TR criteria, a diagnosis of sleep disorder requires that the patient has difficulty falling or staying asleep for at least a month and that there is impairment of daytime functioning.<sup>4,315</sup>

The literature recommends thorough individual assessments of insomnia. Polysomnography (PSG) is the gold standard but involves wiring subjects to record brain and muscle activity.<sup>320</sup> This technique does not allow for naturalistic sleep assessment and is not tolerated well in cognitively impaired people.<sup>347</sup> Actigraphy is less intrusive and involves subjects wearing a wrist monitoring device which measures body movement, based on the assumption that sleeping subjects move less frequently.<sup>320</sup> However, when a recent study compared actigraphy and PSG readings, it was noted that many older people did not move enough when awake for detection.<sup>348</sup> Thus, actigraphy may overestimate sleep time, especially in older people with fragmented sleep.<sup>326</sup>

Direct behavioural observation is commonly used to evaluate sleep, but to be effective needs to be conducted more frequently than twice an hour to capture night awakenings.<sup>347</sup> Subjective sleep quality reports are useful as they may provide insight into individual experiences but data may not be accurate, particularly in residents with cognitive impairment.<sup>320</sup> Data obtained from nursing staff may be the most relevant measure in the RACF setting.<sup>347</sup>

### **6.3.1 Non-pharmacological management of insomnia**

Non-pharmacological management strategies are aimed chiefly at correcting behaviours that are not conducive to healthy sleep.<sup>314</sup> While medications are used more commonly to treat insomnia in older people, several meta-analyses have shown that behavioural strategies are equally effective but effects are longer lasting.<sup>349,350</sup> A review of the efficacy of non-pharmacological treatment for primary insomnia, based on 2 meta-analyses and 48 studies, concluded that 70% to 80% of people with insomnia benefit from non-drug treatment. Time to sleep onset was improved by an average of 30 minutes and wake time after sleep onset was reduced from 70 to 38 minutes.<sup>351</sup> In a RCT directly comparing CBT, temazepam, a combination of both treatments and placebo in 78 older adults with insomnia, all three active treatments significantly improved sleep measures compared to placebo after 8 weeks.<sup>352</sup> However, at 3, 12 and 24 month follow-up measures, patients in the CBT group sustained improvements, whereas sleep measures declined in those patients taking temazepam, both singly and in combination.<sup>352</sup>

Most behavioural approaches emphasise good ‘*sleep hygiene*’ rules (see Table 21), a term coined to describe a variety of scheduling, dietary, environmental and activity recommendations designed to improve sleep.<sup>323,353</sup>

**Table 21: Sleep hygiene rules<sup>323</sup>**

1.	Do not spend too much time in bed
2.	Maintain a consistent sleep/wake time
3.	Get out of bed if unable to fall asleep
4.	Restrict naps to 30 mins in the late morning or early afternoon
5.	Exercise regularly
6.	Spend time outside without sunglasses especially late in day
7.	Increase overall light exposure
8.	Eat a light snack (i.e. milk, bread) before bed
9.	Avoid caffeine, tobacco and alcohol after lunch
10.	Limit liquids in the evening

It should be noted that sleep hygiene measures are generally considered a contributing, not a primary, cause of insomnia in older people.<sup>323</sup> Several large meta-analyses of psychological treatments have shown that treatments based solely on improving sleep hygiene are ineffective in improving sleep.<sup>348,350</sup> The most effective behavioural treatment for insomnia appears to be multi-component CBT.<sup>348,350</sup> The cognitive component of CBT usually educates the patient to have realistic expectations and beliefs about sleep as they age, while the behavioural component usually involves a combination of strategies, including sleep restriction (SR), stimulus control therapy (SCT), relaxation techniques and promotion of good sleep hygiene practice.<sup>323,350</sup>

The strategy of sleep restriction is based on the principle that restricting time in bed helps consolidate sleep. Participants are told to reduce the amount of time spent in bed to correspond with the amount of actual time spent sleeping, (e.g. a person that reports they are in bed for 9 hours but only sleeps 6 hours would be told to limit their time in bed to a single window of 6 hours).<sup>353</sup> This leads to a mild sleep deprivation state; however, as sleep improves within that window, the permitted time in bed is gradually increased until that individual's optimum sleep time is achieved.<sup>312,353</sup> SCT focuses on reducing environmental cues associated with being awake. The participant is advised to go to bed only when sleepy, to leave bed if they can't fall asleep, to adhere to a strict sleep/wake schedule, not to nap and to use the bed only for sleep and sex.<sup>312</sup> Relaxation techniques include meditation, hypnosis, deep breathing and progressive muscle relaxation.<sup>312</sup>

Although the majority of research has been conducted in young adults, CBT has also been shown to be an effective strategy to manage insomnia in older people.<sup>314</sup> For example, one RCT with 92 older participants involved half the sample attending 2-hour CBT sessions per week, while the other half attended stress management sessions. After 8 weeks, the CBT group showed significant improvement in sleep measures compared to the stress management group.<sup>354</sup>

It needs to be mentioned critically that most of the work on CBT comes from academic research settings and not from standard health care environments, especially aged care where sleep disturbance is a major concern.<sup>355</sup> It is not known how effective and acceptable CBT

would be for RACF residents. Another issue is the availability of these types of psychological interventions. It is estimated that, in spite of a large evidence base to support its use, less than 1% of chronic insomniacs world-wide receive CBT.<sup>355</sup>

Many of the non-pharmacological strategies described above are difficult to implement in the RACF setting, partly because of institutional policies, routines and staffing limitations but also because many of the strategies require significant cognitive abilities.<sup>312</sup> In addition there is limited training for health professionals on behavioural therapies for insomnia, difficulty obtaining trained therapists to implement them and limited reimbursement available for psychosocial treatments.<sup>312</sup>

There are, however, other sleep improvement strategies that have been evaluated in RACFs, including exposure to bright light, daytime activities and exercise.<sup>324,328</sup> To date, many trials testing these particular strategies have produced mixed results and there is limited agreement on methodology, such as the duration, intensity and timing of bright light exposure; or the intensity of exercise or type of activities required to achieve optimal effects on sleep.<sup>328</sup>

An alternative approach involves the use of multi-component interventions which address both physiological and environmental causes of sleep disturbance.<sup>328</sup> For instance, a 5-day RCT evaluated the provision of a combination of light exposure, physical activity, structured routines, restricted time in bed plus ‘minimalised’ night-time nursing care.<sup>356</sup> Although various sleep measures improved, including daytime sleepiness, there was little impact of the intervention on night-time sleep. The researchers of this study commented that they were unable to reduce the high level of night time noise and light in the RACF setting, and they also felt that the intervention was required for a longer period in order for night-time improvement to be observed.<sup>356</sup> Table 22 summarises non-pharmacological strategies to improve sleep measures in RACF residents.

**Table 22: Strategies for coping with sleep disturbance in RACF residents<sup>312,320</sup>**

Limit time in bed	Keep the home brightly lit during the day
Avoid serving meals in bed when possible	Encourage exercise that is appropriate
Keep naps to 30 minutes	Keep a regular schedule
Avoid caffeine	Individualise bedtime routines
Keep night-time noise to a minimum	Keep residents rooms dark at night
Place large clocks around the home	Adopt bedtime rituals such as a warm bath
Offer a warm milky drink at night	Reduce night-time nursing care

### **6.3.2 Pharmacological management of insomnia**

There are various pharmacological treatments for insomnia. The most common agents used as hypnotics in older people are benzodiazepines.<sup>357</sup> Hypnotic medications such as the non-benzodiazepines or ‘Z-drugs’ (e.g. zolpidem and zopiclone) and melatonin are also available,



although these agents are not currently subsidised on the PBS.<sup>102,358</sup> Other treatments used to treat insomnia include antihistamines, sedating antidepressants and antipsychotics; however, these medication classes are not specifically licensed for this indication.<sup>323</sup>

The use of a medication to take advantage of its adverse effect profile is a common practice; yet, much of this prescribing is not supported by clinical evidence and is often associated with significant risk, especially in frail older people.<sup>314</sup> In 2005, the U.S. National Institutes of Health concluded that in the treatment of insomnia, the risks associated with the use of 'off-license' agents outweigh the benefits.<sup>332</sup> *Antihistamines*, for instance, possess anticholinergic properties; moreover these agents are not effective when taken on a chronic basis, as tolerance to their sedative effects occurs a week or two after continuous use.<sup>314</sup> The TCAs also have strong anticholinergic effects, potentially leading to postural hypotension, urinary retention, delirium and cardiac arrhythmias. In addition, explicit criteria (Beers criteria) have identified amitriptyline and doxepin as inappropriate for use in older adults due to an unfavourable risk/benefit profile.<sup>359</sup>

*Mirtazapine*, an antidepressant with noradrenergic and serotonergic properties, has improved sleep measures in open-label trials.<sup>360</sup> One study using PSG revealed that total sleep time, REM and slow wave sleep increased during treatment with mirtazapine, and that these effects persisted after 5 weeks.<sup>361</sup> It should be emphasised, though, that all participants in this trial had major depression. Much of the improvement in sleep is most likely due to the treatment and resolution of the underlying depression, rather than direct effects on sleep.<sup>360</sup> There are no known trials that have evaluated mirtazapine for use in primary insomnia, in the absence of depression. Moreover, adverse reactions associated with this drug include paradoxical agitation, exacerbation of RLS, as well as daytime sedation.<sup>312,314,360</sup>

A recent review of antidepressants for the treatment of insomnia concluded that sedating antidepressants could be considered for insomnia if there was a concomitant depressive symptomology.<sup>335</sup> Drugs lacking strong anticholinergic properties should be preferred and the dose should be as low as possible.<sup>335</sup>

#### *6.3.2.1 Benzodiazepines*

Benzodiazepines have been the mainstay of pharmacological treatment of insomnia for more than forty years.<sup>314</sup> Although most people report sleep improvement when treated, benzodiazepine treatment reduces stages 3 and 4 sleep and REM sleep and prolongs stage 2 sleep.<sup>358</sup> As a result, some experts suggest that although the quantity of sleep is increased, the quality of sleep is compromised.<sup>133,357</sup> The main hypnotic agents used in Australia are listed in Table 23.

**Table 23: Hypnotic medications used in Australia<sup>69,119,271</sup>**

Name	Usual dose (mg)	Dose for older people(mg)	Time for onset (min)	Significan metabolism	Duration of effect (hrs)	Half-life (hr)
Temazepam	10-20	7.5-10	30-60	No	6-12	8-22
Nitrazepam	5-10	2.5-5	20-50	Yes	>24	15-38
Oxazepam	15-30	7.5-15	20-50	No	6-12	4-15
Zolpidem	5-10	2.5-5	7-27	No	3-8	2.5
Zopiclone	5-7.5	2.5 – 3.75	15-30	No	< 6	6-9
MelatoninCR	2	2	unclear	No	2-4	3.5-4

A Canadian health study involving a survey of 2 798 community-based older people in 2005 and 2006, found that nearly 25% used benzodiazepines at least once during the year preceding the survey.<sup>159</sup> A relevant finding was that 83% of people taking benzodiazepines still reported problems with sleep; which begs the question whether benzodiazepine are effective hypnotics for older people, especially in the long term?<sup>159</sup> This question is difficult to answer as the majority of published studies on benzodiazepines were conducted before 1995 when trials were less rigorous in design and relatively few RCTs were conducted in older people.<sup>314</sup>

One study assessing the effects of benzodiazepine over the long term often cited in the literature was conducted by Wauquier and Declerk in 21 newly diagnosed insomniacs in the U.S.<sup>362</sup> In 15 of the cases, benzodiazepines were prescribed to treat the insomnia by a G.P. PSG readings were taken at night time of all 21 subjects before treatment, 1 week and 4-6 weeks after benzodiazepines were started. Statistically significant changes in sleep-wake patterns were observed in the benzodiazepine treated participants one week after starting them: Sleep onset was shorter, Stage 2 sleep was increased and there were fewer awakenings.<sup>362</sup> However, these effects could no longer be measured 4 to 6 weeks later. Interestingly, the number of awakenings was higher in benzodiazepine treated subjects at 4-6 weeks than before they commenced treatment. This study has many limitations. Firstly, the age of the participants is not revealed, the control group results are not compared to the benzodiazepine treated group, the benzodiazepine agents prescribed varied widely in type and dose and the sample is small.<sup>362</sup>

In Holbrook *et al*'s large meta-analysis of benzodiazepine use to treat insomnia, only 15 of 45 RCTs included patients over 65 years of age.<sup>363</sup> Likewise, in Glass *et al*'s recent meta-analysis of sedative use in older people, only 14 RCTs comparing benzodiazepine treatment with placebo met inclusion criteria.<sup>364</sup> Furthermore, neither meta-analysis included studies longer than 2 to 4 weeks, despite the fact that in practice, many people take benzodiazepines for much longer.<sup>312,363,364</sup> In terms of effectiveness, Holbrook *et al*. found that benzodiazepines decreased time to fall asleep by an average of 4.2 minutes (95% CI: -0.7 - 9.2, non-sig) compared to placebo; however, total sleep duration increased by 48 minutes (95% CI: 40 - 57,  $p < 0.05$ ).<sup>363</sup> Glass *et al*'s meta-analysis, which specifically targeted treatment of older people,

reported that the number of awakenings reduced with benzodiazepine use, and that total sleep duration increased by 34 minutes (95% CI: 16 – 53,  $p < 0.01$ ).<sup>364</sup> The difference in sleep duration between the two meta-analyses strongly suggests that benzodiazepines benefit older people less than younger patients.<sup>364</sup>

In terms of adverse events, Holbrook *et al.* found a significant increase in adverse events with benzodiazepine use, especially daytime drowsiness and dizziness: AOR 1.8, (95% CI: 1.4-2.4).<sup>363</sup> Glass *et al.*'s meta-analysis reported much higher rates of daytime fatigue, cognitive effects and psychomotor impairment (AORs: 3.8, 4.8 and 2.6, respectively); signifying that older people are likely to have greater potential for adverse events.<sup>364</sup> Glass *et al.* theorised that this increase in adverse event rate is due to the differences in benzodiazepine pharmacokinetics between older and younger people.<sup>364</sup> They concluded their meta-analysis by stating:

*“Although the improvements in sleep variables are statistically significant, the effect size is small, and the clinical benefits may be modest at best. The added risk of an adverse event may not justify these benefits, particularly in a high-risk elderly population.”*<sup>364</sup>

The optimum benzodiazepine for an older person should have a rapid onset of action and a relatively short elimination half-life.<sup>314</sup> Individualising treatment to cater for different types of insomnia symptoms is recommended.<sup>347</sup> For sleep-onset insomnia, a short-acting agent such as oxazepam may be effective; however, in a patient with early morning awakening, an intermediate-acting agent such as temazepam may be a better option.<sup>358</sup> Although the use of short-acting benzodiazepines is associated with less likelihood of daytime drowsiness, these agents are associated with a higher rate of dependence. On the other hand, longer-acting agents are associated with less dependence potential but greater daytime impairment.<sup>314</sup>

### 6.3.2.2 Z-drugs

The ‘Z-drugs’; zolpidem and zopiclone, were introduced to Australia in the early 1990s. Like benzodiazepines, Z-drugs bind to the GABA receptor; however, unlike benzodiazepines, Z-drugs have selective binding affinity for different receptor subtypes, which may account for their predominant effects on sleep as opposed to anxiety.<sup>365</sup> In general, the Z-drugs are absorbed more rapidly than benzodiazepines and possess shorter half-lives, meaning their primary action is on sleep onset rather than sleep maintenance.<sup>357,358</sup>

The NICE guidance on Z-drugs, published in 2004 and recently upheld in 2010, reported outcomes from 17 RCTs with a total of 1284 patients. NICE concluded that all treatment durations in the RCTs were very short (maximum of 6 weeks) and that no consistent difference was found between the Z-drugs and benzodiazepines for either effectiveness or safety.<sup>366</sup> There

is limited direct comparative data on the use of benzodiazepines and Z-drugs specifically in older people.<sup>367</sup> In Glass *et al*'s meta-analysis, 3 studies involving 339 older patients indicated no significant difference in sleep quality between benzodiazepines and the Z-drugs.<sup>364</sup> Six studies involving 648 older patients found no significant difference in adverse effects either, leaving the authors to conclude that the Z-drugs offered few, if any, clinical advantages over benzodiazepines in efficacy or tolerability in older people.<sup>364</sup>

#### **6.3.2.3 Melatonin**

Melatonin affects sleep/wake regulation but also facilitates sleep directly.<sup>368</sup> As the half-life of endogenous melatonin is less than an hour, a prolonged-release preparation has been developed to mimic the physiological release of the hormone.<sup>368</sup> This preparation has recently been approved in Australia as short-term therapy for primary insomnia in patients over 55 years.<sup>369</sup> Prolonged-release melatonin has been shown to reduce time to sleep onset by about 9 minutes and increase subjective sleep quality in two large trials in people over 55 years.<sup>370,371</sup> The effect sizes in both trials were modest, with clinically meaningful improvements in sleep only occurring in about a third of patients. Adverse reactions have not been thoroughly evaluated to date, but the use of prolonged-release melatonin does not appear to cause daytime drowsiness or dependence.<sup>369</sup> At present, melatonin is only approved for a maximum of 13 weeks as there is insufficient evidence to support long-term use.<sup>369</sup> In addition, the role of this product in RACF patients with dementia is unclear, with a recent RCT involving 41 patients, concluding that treatment with prolonged-release melatonin produced no significant effects on sleep or agitation.<sup>372</sup>

### **6.4 Guidelines for the use of benzodiazepines**

Several Australian professional bodies, including the Royal College of General Practitioners and the Royal Australian and New Zealand College of Psychiatry have developed guidelines for the use of benzodiazepines, though these were published over 10 years ago.<sup>95,373</sup> Both guidelines emphasise non-drug treatment strategies first-line, time-limited benzodiazepine use, regular review and tapering of long-term treatment.<sup>95,373</sup>

Glass *et al*'s meta-analysis of hypnotic agents in older people calculated that the number needed to treat for improved sleep quantity was 13; however, the number needed to harm for any adverse event was 6.<sup>364</sup> This unfavourable risk/benefit ratio has led authorities to caution against use in this age group, and warn that older people taking hypnotics should be monitored closely.<sup>271</sup> A prescribing practice review on management options for improving sleep was recently published by the National Prescribing Service (NPS) (Table 24 summarises key messages).<sup>374</sup>

**Table 24: Key messages: Management options for improving sleep**<sup>374</sup>

- 
- Explore patient concerns with sleep difficulties – identify and address causes
  - Offer behavioural and cognitive therapies for insomnia
  - Discuss and specify the duration of hypnotic medicine use with patients/carers
  - Trial discontinuation of hypnotic medicines in long-term use
  - Minimise potential harms of hypnotic medicines by engaging patients/carers in managing sleep difficulties
- 

Similarly, the AMH Drug Choice Companion: Aged Care recommends a full evaluation as the first step in the management of insomnia followed by sleep hygiene measures and strategies including light therapy.<sup>272</sup> The use of hypnotic medication is not recommended as a first-line step; when used, the reference states they should be used for short periods only and suggests that a definite time limit for hypnotic treatment be agreed with the patient. Finally, the AMH Drug Choice Companion, unlike many other international and national guidelines, recommends strategies to achieve benzodiazepine withdrawal.<sup>272</sup> The majority of guidelines for benzodiazepines emphasize that treatment should be time-limited, usually to periods of 2-3 weeks, due to the perceived risk of tolerance.<sup>95,332,373</sup> However, there is considerable debate over the association between benzodiazepines and dependence. Some clinicians report that tolerance to the effects of these medications, with resultant dose escalation, is actually quite uncommon in actual practice.<sup>158,348</sup> They argue that guidelines on duration of use are not based on direct evidence of dependency from clinical trials, but instead exist because there is a lack of high quality RCT evidence on benzodiazepine use extending past 2-3 weeks.<sup>158,375</sup>

On the other hand, other researchers propose that tolerance develops with most hypnotic drugs and that to maintain efficacy, the dosage is often increased, or additional hypnotics added.<sup>154,376</sup> When most people try to stop benzodiazepines, a phenomenon known as ‘rebound insomnia’ occurs where the person experiences worse insomnia symptoms than those which prompted them to seek assistance in the first place.<sup>376</sup> Rebound insomnia is usually temporary, mostly lasting for a few days, though the duration and intensity appear to be related to both benzodiazepine half-life and dosage.<sup>158</sup> Some researchers hypothesise that the experience of rebound insomnia reinforces the belief that the person cannot sleep without the medication and this explains why they continue to take them.<sup>376</sup> Like long-term RCT data, evidence to support this hypothesis is lacking. It is simply not known how many long-term benzodiazepine users are afraid to try discontinuation because of experience with rebound insomnia, or the proportion who still have difficulty sleeping while taking benzodiazepines.<sup>158</sup> High-quality studies are urgently needed to inform evidence-based recommendations on the optimum duration of use of hypnotic agents in older people.

## CHAPTER SEVEN: THESIS OBJECTIVE AND AIMS

### 7.1 Introduction

Although non-pharmacological strategies have shown effectiveness to manage BPSD, anxiety and sleep disorders, the use of antipsychotic and benzodiazepine medication to treat these conditions in RACFs is widespread, with high rates of use, as reflected in the proportion of residents taking the drugs regularly, reported in the majority of research publications and government audits of prescribing data nationally and internationally for over thirty years.<sup>42,83,90</sup>

In an attempt to address this situation, many professional bodies and government authorities have released ‘good practice’ guidelines and also implemented pharmacist-led initiatives to ensure the appropriate psychotropic prescribing and timely review of these medications in RACFs.<sup>94-96,271,373</sup> Although derived from up-to-date evidence-based research, psychotropic medication guidelines do not appear to be adhered to. In a similar fashion, medication reviews do not appear to significantly impact RACF antipsychotic and benzodiazepine use, with 33%-80% of residents prescribed at least one of these drugs for extended periods in the majority of published studies.<sup>87</sup> Furthermore, researchers in Australia, the U.K and the U.S have reported that the prevalence of antipsychotic use in RACFs appears to be on the increase.<sup>91,101,377,378</sup>

### 7.2 The Quality Use of Psychotropic Medication in Australian RACFs

The supposition that rates of psychotropic use remain elevated in Australia in particular is somewhat surprising because one of the main justifications for the present pharmacist-led RMMR program and associated QUM services was to address the high rates of psychotropic medication use found in the residential aged care setting.<sup>46</sup> While these practice developments represent a significant step forward, measurable effects of these federally-funded initiatives on psychotropic use in RACFs are limited owing to a scarcity of published research data.<sup>47</sup> Some evidence of a change in psychotropic prescribing patterns was evident in a study conducted by Snowden *et al.* in 50 RACFs in Southern Sydney during 2003 where benzodiazepine use was observed to fall markedly over a ten year period.<sup>90</sup> This period coincided with the introduction of RMMRs and practice based guidelines from NSWHealth.<sup>242</sup> Although Snowden *et al.* attributed the reduction to these innovations, they also considered that media attention resulting from their original study played an important role. Although benzodiazepine rates did fall sharply, it should be acknowledged that antipsychotic prevalence remained unaltered in the follow-up study.<sup>90</sup> Another study, conducted in Western Australia in 2010, long after RMMRs and QUM services were introduced, audited psychotropic use in 351 RACF residents with

dementia. A third of the sample (35%) were prescribed antipsychotic treatment, 21% were taking anxiolytics and 28% of the sample were using hypnotic medications.<sup>379</sup> Judging from these studies, it appears that psychotropic use in Australian RACFs continues to be high.<sup>90,379</sup>

### **7.2.1 Professional Guidelines relating to psychotropic use in older people and RACFs**

There are a multitude of national and international guidelines, along with a number of 'good practice' guides, which aim to promote the quality use of psychotropic medication in older people.<sup>94,96,261</sup> Clinical guidelines have been published by professional bodies, including the RACGP, the ANZCP and the IPA.<sup>94,96,261</sup> Furthermore, government funded educational organisations, including the NPS, MATES, the AMH group and Therapeutic Guideline Committee have all produced their own psychotropic guidelines.<sup>119,164,244</sup> Government Departments of Health; for example, NSWHealth and the Western Australian Department of Health, have also published clear and informative guidelines aimed to specifically promote quality use of psychotropic medication in RACFs.<sup>242</sup> It is not known which of these guidelines are promoted and utilised in Tasmanian RACFs. However, in spite of the considerable choice and high quality of these guidelines, psychotropic use in the residential aged care setting continues to be problematic.

### **7.3 Implementing evidence-based practice**

Abundant research data both nationally and overseas suggests that evidence-based quality use of psychotropic medication is not taking place in the residential aged care setting.<sup>91,101,377,378</sup> This situation is not unique to this particular group of medications, nor within the aged care setting. There is substantial evidence of the failure to translate evidence based research into actual practice: it is thought that 30-40% of patients do not receive treatments of proven effectiveness and that up to a quarter of patients receive care that is not needed or harmful.<sup>380</sup> It is important to acknowledge that the mere existence of evidence around the efficacy and safety of a therapy does not automatically translate into appropriate use of that therapy.<sup>381</sup> Traditional approaches to improve the uptake of evidence based medicine have focused on improving the availability and presentation of evidence by disseminating evidence in clinical guidelines and journals, continuing medical education courses and conferences.<sup>382</sup> However, with the rapid advances in health-care knowledge and the volume of clinical research data currently in circulation it is difficult for health practitioners to keep up with the evidence, let alone incorporate it into practice.<sup>382</sup>

Even if health professionals are aware and familiar with the research evidence, many barriers exist to its uptake. Authors of a review of 76 studies in physicians concluded that obstacles to change in practice can arise at different stages in the health-care system; at the

patient level, the individual professional level, the health-care team level, the health-care organisation, or the wider environment.<sup>383</sup> In residential aged care, where all of these stages come into play, changes in practice would be difficult to achieve.

There is growing interest in evaluating and developing effective strategies to encourage the adoption of best evidence into practice (also referred to as implementation research); however, it is commonly agreed that the implementation of new evidence into practice requires a change in human behaviour which is complex and more often requires multi-strategic interventions for success.<sup>384</sup> Implementation research aims to increase understanding of the influences on healthcare professionals' behaviour and also aims to determine which methods enable them to use research findings more effectively.<sup>385</sup>

In 2005, the UK Medical Research Council proposed a framework for the development and evaluation of complex interventions, such as interventions designed to enhance the uptake of research findings.<sup>386</sup> This framework recognises the need to:

- Establish the theoretical basis for a given intervention;
- Define the components of the intervention;
- Undertake exploratory studies to elect strategies and refine interventions; and
- Conduct a definitive evaluative study, preferably a RCT.<sup>386</sup>

#### **7.4 The main objective: An Intervention Project**

Despite a multitude of professional guidelines, the federally funded RMMR program and associated QUM services, and policy/regulatory QUM framework around RACF accreditation, the use of psychotropic medication in RACFs, particularly antipsychotics and benzodiazepines, continues to be high.<sup>90,379</sup> Although many researchers have reported high prevalence rates of these medications in RACFs, few intervention projects have specifically aimed to ensure the quality use of psychotropic medication in this environment, especially in Australia. Thus, the main objective of this research thesis was to design, trial and evaluate a dedicated pharmacist-led intervention project to promote the quality use of benzodiazepines and antipsychotics in RACFs. Before the intervention could be developed, a theoretical basis for it needed to be defined. Following this, an extensive review of the literature on the management of old age mental health conditions was conducted to determine what exactly is evidence based good-practice? Before proceeding further, vital background pre-intervention research was required to determine the present utilisation pattern of benzodiazepines and antipsychotics in Tasmanian RACFs and also attain a greater understanding of the determinants underlying the use of these psychotropic medications. For this reason the research for this thesis was conducted in four stages which will be outlined later in this chapter.



#### **7.4.1 Theoretical basis for the intervention project**

It is argued that theories such as social cognitive theory, communication theory, social marketing, organizational change, political science and economic theory should underpin research to improve medication use.<sup>384</sup> The use of these theories and models to inform an intervention should increase the likelihood of success because it will then be planned with knowledge of factors influencing learning, behavioural change and communication, as well as consideration of the regulatory, organisational and political factors.<sup>384</sup> The theoretical framework selected for the proposed RACF psychotropic intervention project combined a number of psychological and marketing theories, including persuasion communication theory, social cognition theory, and the transtheoretical and the PRECEDE-PROCEED models.

Persuasive communication is '*the conscious attempt to change the behaviour of another through the transmission of a message designed to change attitudes, beliefs or behaviour*'.<sup>387</sup> The effectiveness of persuasive communication depends on the interaction between the communicator, audience, message and the way in which the message is delivered.<sup>387</sup> Key aspects of this model include: that the more relevant a message is to the individual, the more attentive they will be to the message; that it is vital to actively involve the audience, for example, through discussion; and finally, that repetition of the message increases its persuasiveness.<sup>384</sup> The persuasiveness of a message is also affected by the medium through which it is transmitted, with face-to-face communication usually more effective than telephone or mail-outs. More complex messages requiring greater comprehension are more persuasive when provided in the written form.<sup>384</sup>

While persuasion communication models explain which aspects of communication are likely to influence attitude change they stop short of explaining how this actually translates into behavioural change.<sup>384</sup> Social cognitive theory and the transtheoretical model provide frameworks that have been developed to describe and predict learning and behaviour change. Where the persuasion model notes the importance of cognitive processing of messages, social cognitive theory recognises that the human capacity for knowledge and the ability to symbolise and imagine can facilitate behaviour change.<sup>388</sup> How a person perceives themselves and their ability for self-reflection and self-regulation, or their 'self-efficacy', influences and informs behaviour. Those with high self-efficacy are more likely to have greater motivation, set higher goals for themselves and persist longer with a given behaviour.<sup>384</sup> It is important to note that a person must believe that the outcome of a given behaviour is beneficial otherwise they will be unlikely to perform it. However, to be able to determine if the given behaviour is worthwhile they need to cognitively process diverse sources of information through direct experience, observation, verbal persuasion and affective responses.<sup>384</sup> An effective intervention will ideally incorporate opportunities for all four types of social cognitive processes.

Social cognitive theory describes how learning a behaviour occurs but the transtheoretical model explains the progressive nature of behavioural change.<sup>384</sup> This well-known model postulates five stages through which people progress in adopting new behaviours: pre-contemplation, contemplation, preparation, action and maintenance. When applied to an intervention, various strategies should be tied to the defined stage of change. For instance, awareness-raising strategies are only useful for persons in the pre-contemplation and contemplation stages, yet those in the preparation and action stages require active strategies that encourage the practice of new behaviours.<sup>389</sup>

The 'PRECEDE-PROCEED' health program planning model offers another perspective when considering ways to enhance the uptake of evidence by incorporating both individual behaviour change and public health principles.<sup>390</sup> PRECEDE is an acronym that stands for 'predisposing, reinforcing and enabling factors in educational diagnosis and evaluation'. This component of the model highlights the need to target interventions not only to predispose individuals towards certain behaviour but also to enable and reinforce the behaviour. PROCEED stands for 'policy, regulatory and organisational constructs in educational and environmental development'. This component of the model recognises the need to address the regulatory, political and organisational factors that may impact on the success of an intervention.<sup>390</sup> This model highlights the need to understand the barriers of change, as well as the predisposing and enabling factors, both at the individual and environmental levels, before the intervention is conducted.<sup>384</sup>

The persuasive communication and social cognitive theories, and the transtheoretical model identify the need to encourage involvement and maximise social cognitive processing. They also highlight the need for continued repeated provision of information and opportunities for individuals to practice their new behaviour. Further, they suggest messages must be tailored and targeted to pre-identified groups. Importantly, the PRECEDE-PROCEED model identifies the need for understanding barriers and enablers for change before developing the intervention. Finally, all four theories and models identify the need for monitoring and feedback activities within the intervention to encourage refinement of the new behaviour.<sup>384</sup> How the theoretical basis was practically applied in the intervention study will be covered in part four of this thesis.

## **7.5 The components of the intervention**

As part of the framework for the development and evaluation of this intervention it was important to develop a thorough understanding of the issue of psychotropic use in RACFs. To this end, the first stage (part one of the thesis) involved a detailed search of the scientific literature to determine the benefits and risks associated with antipsychotic and benzodiazepine use in older people. Part one also aimed to consider the diagnostic features and evidence-based

treatment of old age mental health disorders. It was also important to elucidate the policy and regulations associated with QUM processes and define the role the pharmacist currently plays to improve QUM in RACFs.

The next two stages of the research, (parts two and three of the thesis) comprised the exploratory components of this research. The aim of these two pre-intervention stages was to obtain vital background information regarding the prevalence, quality and extent of variation of psychotropic use in Tasmanian RACFs and also to increase our knowledge of why antipsychotics and benzodiazepines are used so widely in this setting.

### **7.5.1 Two exploratory stages**

The current prevalence and characteristics of psychotropic medication use in Tasmanian RACFs is unknown. The last known published study was conducted in 1993 by Munro *et al.*, revealing some of the highest rates of benzodiazepine and antipsychotic use in Australia.<sup>84</sup> For this reason, the second stage of this thesis (part 2) aimed to ascertain the current prevalence, quality and pattern of RACF psychotropic use in Tasmania. Apart from obtaining an update on psychotropic prevalence and dosing in RACFs, it was vital to assess the quality of prescribing and concordance with professional guidelines in order to identify the appropriateness of psychotropic use. Tasmanian RACF psychotropic use was compared with previous Tasmanian studies and also with studies conducted nationally and abroad to highlight key areas of concern.

To achieve this, stage two involved conducting a retrospective cross-sectional study of prescribing data in a large representative sample of RACFs throughout Tasmania. As professional guidelines also recommend that psychotropic medications are reviewed and dose reductions attempted routinely, the cross-sectional study was repeated 12 months later with the objective of evaluating the extent of variation in psychotropic medication and doses administered in the same sample of RACFs.

There are many influences on prescribing practices in the RACF setting. Some of these influences are externally imposed (external factors) such as professional guidelines, restrictions on quantity or indication imposed by the Pharmaceutical Benefits Scheme.<sup>102,391</sup> Other influences, or 'internal factors', specifically resident, GP, staffing and facility characteristics, also affect prescribing practices.<sup>391</sup>

Several international studies have found that nursing staff play the central role in decisions to prescribe medications such as anti-bacterials for urinary tract infections.<sup>392,393</sup> GPs in these studies said that they accepted the nursing staff's assessment of the resident and seldom visited a RACF patient in relation to a urinary tract infection.<sup>393</sup> Whether this would apply to other clinical decision making scenarios, especially those relating to the treatment of mental health conditions, has not been the subject of published research to date. An all-party

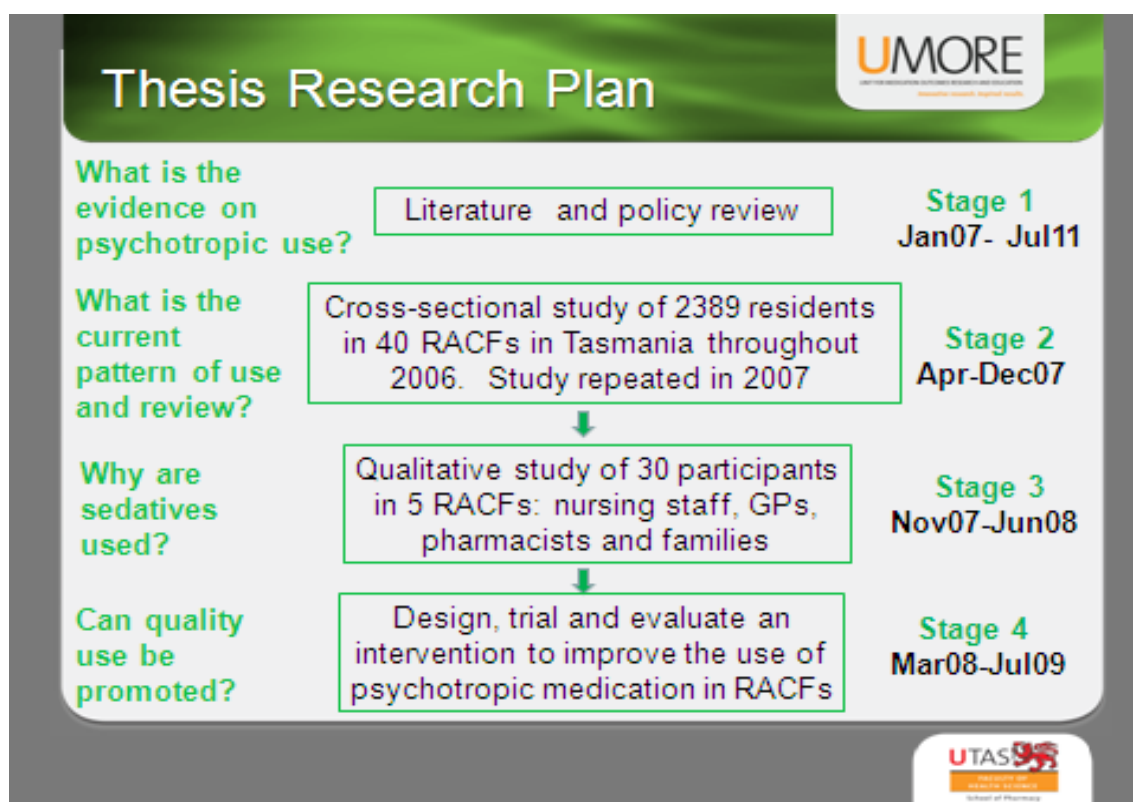
parliamentary committee group on dementia in the U.K. recently stated that ‘*there is limited published data on who initiates antipsychotic prescribing in people with dementia*’.<sup>394</sup> The same can be said about who initiates benzodiazepine prescribing. Therefore, before engaging in the active intervention an important aim of this thesis was to obtain a greater understanding of the influences, or ‘determinants’, on antipsychotic and benzodiazepine prescribing in the RACF setting.

The timely review of psychotropic medications is endorsed by all known professional guidelines, is an essential component of RMMRs and is promoted by QUM services.<sup>46</sup> However, several studies have shown that many residents of RACFs are left on these medications for extended periods.<sup>88,395</sup> Another important objective then, was to gain an understanding of the main barriers to the review of psychotropic medication and determine who exactly is responsible for this task in the RACF setting. With this information, an appreciation as to why these medications are used so extensively in the residential aged care setting can be gained.

Therefore, Stage three (part three of this thesis) adopted a qualitative approach involving thematic analysis of semi-structured interviews with health professionals and relatives to answer key research questions relating to the determinants of antipsychotic and benzodiazepine use in RACFs, including why these medications are used in this setting and who is influencing their initiation and review? Another aim of Stage 3 was to examine the current role of the pharmacist and in ensuring quality use of psychotropic medication in RACFs. As there is a paucity of qualitative research related to psychotropic use in the residential aged care setting, this study provided valuable insight into the issue of continued high rates of use.

### **7.5.2 Overall Research Plan**

Applying the findings from the first three stages, the fourth and main stage of the thesis aimed to design, conduct and evaluate an intervention project, trialling strategies provided by community pharmacists, to facilitate the quality use of antipsychotic and benzodiazepine medications in RACFs. This fourth stage involved a large controlled intervention trial run in 25 RACFs in the two major cities of Tasmania and was termed the ‘Reducing Use of Sedatives’ (RedUSE) project. Although the intervention trial was conducted primarily through community pharmacy, the project was designed to be interdisciplinary in nature, involving nursing staff, GPs, pharmacists and relatives of RACF residents. A summary of the Thesis Research Plan, highlighting the four main project stages is illustrated as follows:



### 7.5.3 Post-evaluation of the intervention

Although several intervention projects aimed at improving RACF psychotropic use have been published, few studies have reported costing data, clinical outcomes for residents or evaluated the sustainability of the intervention project over the long term. Consequently, various post-analyses of intervention data were conducted which aimed to evaluate the clinical impact of the project on residents in terms of falls and behaviour rate; and to perform an interim costing analysis. A final aim was to determine the long-term impact of the intervention; therefore, a final follow-up audit measure was performed 12 months after the project was completed.

The intervention project outlined in this thesis was the first Australian intervention trial to assess the effectiveness of pharmacist-led strategies specifically to reduce the use of antipsychotic and benzodiazepine agents in RACFs. A successful reduction of prevalence rates and decreases in doses of antipsychotic and benzodiazepine medication has the potential to offer significant benefits for frail older people in aged care, including increased mobility and alertness, decreased fall rate and improved well-being.<sup>396</sup>

The objectives and aims of this thesis can be summarised as follows:

- The main objective was to design, trial and evaluate a dedicated pharmacist-led intervention project to promote the appropriate use of benzodiazepines and antipsychotics in RACFs.

Before the intervention trial could be undertaken the following aims were defined:

- To ascertain the current prevalence, quality and pattern of RACF psychotropic use in Tasmania;
- To evaluate the extent of variation in psychotropic medication and doses administered in RACFs within a year of data collection;
- To obtain a greater understanding of the determinants of antipsychotic and benzodiazepine prescribing in RACFs; and
- To gain an understanding of the main barriers to the review of psychotropic medication and determine who exactly is responsible for this task in the RACF setting.

As there is an acknowledged scarcity of data on clinical outcomes, costing implications and the long-term impact of RACF psychotropic intervention trials, the final aims of the thesis were:<sup>397</sup>

- To evaluate the clinical impact of the intervention project on residents in terms of falls, behaviour rate;
- To perform an interim costing analysis; and
- To determine the long-term impact of the intervention.

**PART TWO: PSYCHOTROPIC MEDICATION USE IN TASMANIAN  
RESIDENTIAL AGED CARE FACILITIES:**

**A cross-sectional retrospective prevalence study**

## CHAPTER EIGHT: INTRODUCTION

### PSYCHOTROPIC USE IN RACFS

#### **8.1 Psychotropic use in Residential Aged Care Facilities**

For several decades, high prevalence rates and indications of inappropriate use of psychotropic medication in RACFs have been reported, particularly for antipsychotics and benzodiazepines.<sup>17,38,90,91,398</sup> Researchers from the U.S. were the first to draw attention to high rates and dubious quality of psychotropic use in their RACFs. In a study examining psychotropic prevalence using data from the 1984 U.S. National RACF Survey, it was noted that a fifth of residents taking psychotropic medication had no recorded diagnosis of a mental health disorder. It was also noted that more than a quarter of residents were taking two or more psychotropic medications concurrently.<sup>399</sup> Another U.S. study from 1994 compared hypnotic use between RACF residents and in-patients of hospital geriatric wards, concluding that RACF residents were significantly more likely to be prescribed psychotropic medications (45% vs. 34%).<sup>400</sup> In 1988, Beers *et al.* reported that over a quarter of residents in a sample of U.S. RACFs were taking antipsychotic medication and 40% were taking hypnotic medication. Beers *et al.* also drew attention to the high rate of ‘prn’ or ‘as required’ prescribing of antipsychotics and benzodiazepines, meaning that nursing staff were often deciding when and which residents would take this medication.<sup>401</sup>

Yet, high prevalence and inappropriate psychotropic use in RACFs at this time was not confined to the U.S. Studies from Ireland, Norway and the Netherlands around the same period also found psychotropic prescribing to be of dubious quality and highlighted high rates of antipsychotic and hypnotic medication use.<sup>402-404</sup> Of all the countries antipsychotic rates were the highest in the Netherlands (58%), where only residents with dementia were audited, but rates were also high in RACFs in Norway (33%) and Ireland (27%).<sup>402-404</sup> Hypnotic prevalence rates were also elevated, with regular use reported in 42% and 32% of Irish and Dutch residents, respectively.<sup>402,404</sup> As rates of anxiolytic use were not recorded in any of these early studies, the overall rate of benzodiazepine use was probably higher. Apart from high rates of psychotropic use, these European studies noted inappropriate indications, psychotropic drug combinations, and the Dutch researchers noted that as many as half of all RACF residents with dementia showed side effects of psychotropic medication such as parkinsonism.<sup>402-404</sup>

##### **8.1.1 Australian RACF psychotropic use in the 1980s and mid-1990s**

The first major Australian study of psychotropic utilisation was conducted in a group of 46 RACFs in Central Sydney during 1993 by Professor John Snowdon. The rates of regular



antipsychotic (27%), hypnotic (27%) and anxiolytic (9%) benzodiazepine use were proclaimed to be, '*among the highest reported in the world*'.<sup>38</sup> As a consequence, Snowden's study attracted considerable media and public attention, resulting in the establishment of several Government committees to examine the high rate of psychotropic medication use in RACFs. In 1997, NSW Health released the report of the NSW Ministerial Taskforce into 'Psychotropic Medication Use in RACFs'.<sup>39</sup> One of the objectives of the Taskforce was to review current practice in relation to the use of psychotropic medication in RACF residents. As part of their report, the Taskforce commissioned a large literature review with the aim of investigating psychotropic use in RACFs from 1985 to 1996.<sup>39</sup>

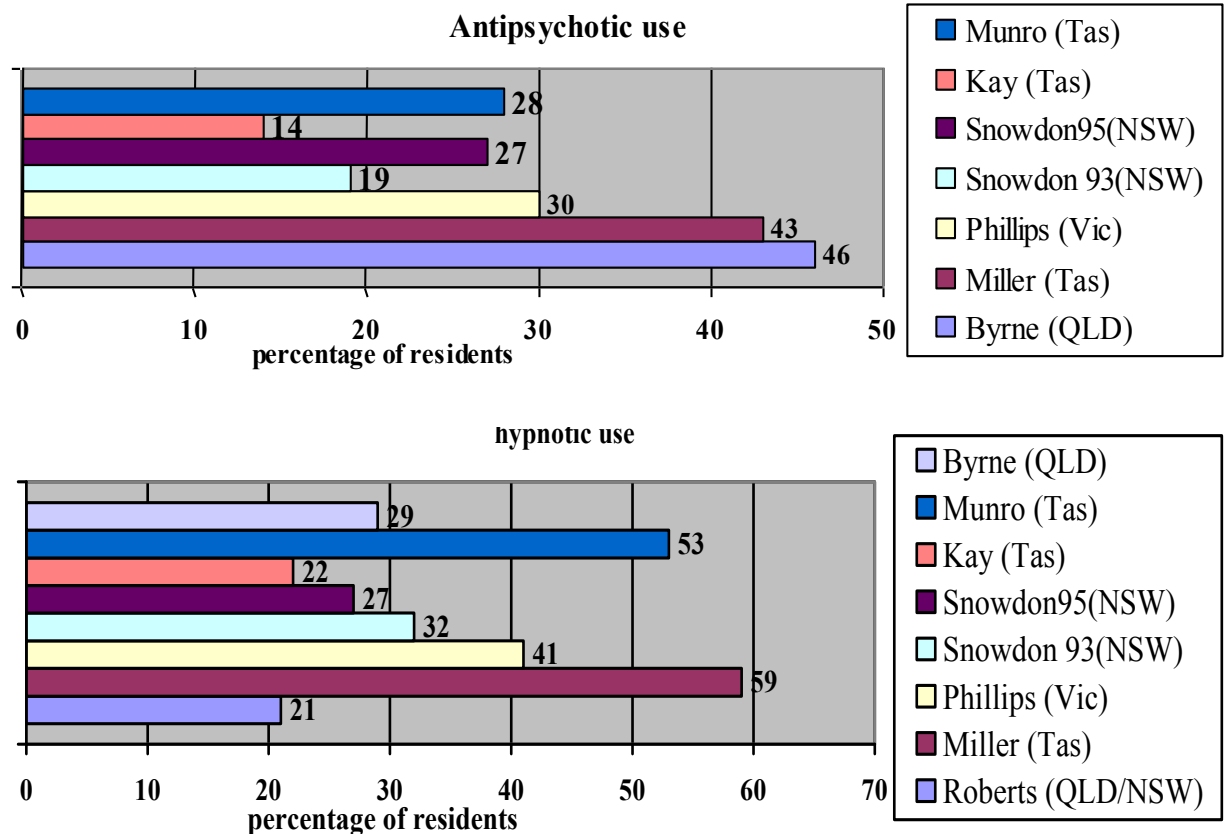
Twenty-five studies were identified by the Taskforce for the review, of which nine were conducted in Australia. The majority of studies were cross-sectional surveys (13) or retrospective medication record reviews (8). The international studies consistently suggested inappropriate use of psychotropic use, including high prevalence rates, wide variation in prescribing practices across facilities, inconsistency with clinical indications, excessive dosages and long duration of treatment.<sup>39</sup> Notably, all nine Australian studies reported inappropriate use of psychotropic medication.<sup>39</sup> Out of the Australian RACF studies (2 unpublished), three were conducted in Tasmania, two in NSW, and one, respectively, in Victoria, Queensland, Queensland/NSW and all states. There was considerable variation in sample size, from 89 to 14 997 residents, and number of RACFs included in each study, from 5 to 46.<sup>39</sup>

The prevalence of RACF antipsychotic and hypnotic use reported in the Australian studies is shown in Figure 12 below. It should be noted that the Queensland study (Byrne *et al.*) was purposely conducted in facilities with high psychiatric morbidity, so the results from this study may not be representative.<sup>405</sup> In summary, antipsychotic prevalence, as reflected in the proportion of residents taking these medications, ranged from 14% to 46% and hypnotic rates of use varied from 21% to 59%.<sup>39</sup> The use of anxiolytic medication was not systematically reported in these studies. As previously mentioned, this means that the overall use of benzodiazepine medication in these studies is likely to be higher.

Apart from high rates of antipsychotic and anxiolytic use, concerns were raised about the high rate of combination psychotropic use, excessive dosages and duration of use of psychotropic agents. In general, the NSW Ministerial Taskforce concluded there was widespread psychotropic use in Australian RACFs but that use in Australia was not radically different from that reported in other countries.<sup>39</sup> Wide variability in psychotropic use between research studies was also noted, even between studies within the same states, which was attributed to differences in study methodology or actual prescribing practices.<sup>39</sup> It is notable that the highest rates of hypnotic use (53% and 59%) were recorded in two of the three Tasmanian studies.<sup>84,406</sup> In contrast, Kay *et al.* reported a low rate of hypnotic use in the remaining Tasmanian study

(22%); however, the sample size of RACF residents was low (89 residents in total) and psychotropic use was loosely defined as ‘past or present’, which, as the NSW Health Taskforce noted, does not provide an appropriate assessment of current drug prevalence.<sup>39,407</sup>

**Figure 12: Psychotropic prevalence rates in Australian RACFs 1980s to mid-1990s**



### 8.1.2 Psychotropic use in U.S RACFs after OBRA-87

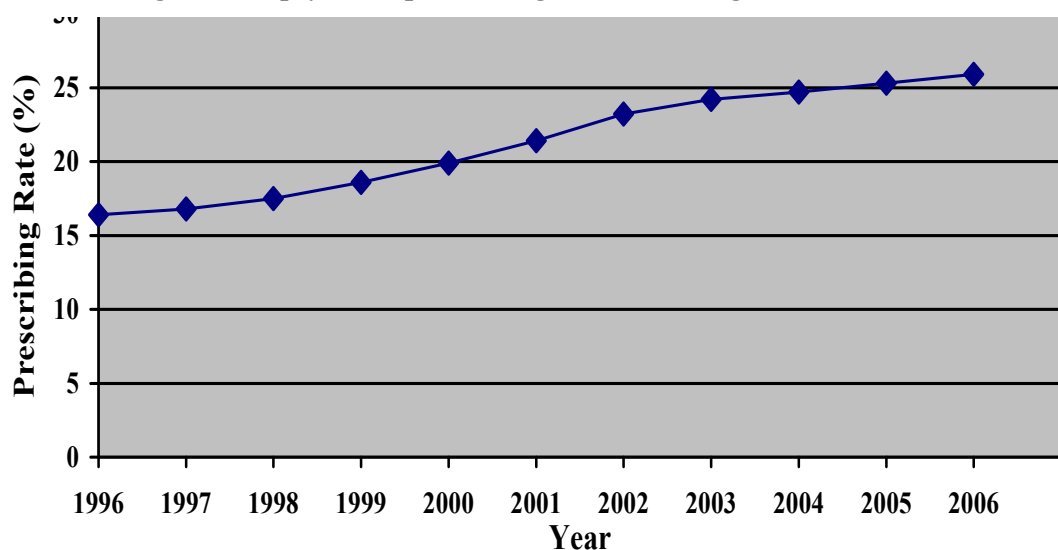
After widespread publicity and consequent federal investigations resulting from the initial U.S. RACF psychotropic studies, the U.S. Congress passed legislation on medication use: the ‘RACF Reform Act’, which was embedded in the ‘*Omnibus Budget Reconciliation Act of 1987*’ (OBRA-87).<sup>47,408</sup> Specifically, the OBRA-87 statute came into effect in 1990 and is implemented through prescribing ‘guidelines for long-term care facilities’ that are routinely updated.<sup>409</sup> According to the latest guidance published in 2006, all psychotropic prescriptions must have an approved indication, doses should not exceed stipulated maximum daily doses, residents taking these medications should be reviewed at least four times a year and dose reduction attempts are mandated six-monthly.<sup>409</sup> RACFs that fail to meet these regulations are subject to a series of sanctions, ranging from financial penalties to closure of the facility.<sup>47</sup>

Initially, OBRA-87 made a significant impact on reducing the rate of antipsychotic prescribing in U.S. RACFs. For example, in Rovner *et al*’s study of 17 facilities in Baltimore,

the prevalence of antipsychotic prescribing declined by 36% six months after the OBRA-87 regulations were enforced.<sup>410</sup> The initial focus of the OBRA-87 legislation was on antipsychotic drugs; however in 1994, specific guidelines were released with the aim of reducing the unnecessary use of benzodiazepines in U.S. RACFs.<sup>411</sup> The revised guidelines defined benzodiazepines as unnecessary if they were used in excessive doses, without appropriate indication or if they were used for longer than 10 days for hypnotics and 4 months for anxiolytics.<sup>411</sup> These revised guidelines did not appear to exert the same effect on benzodiazepine prescribing as the initial OBRA-87 legislation exerted on antipsychotic prescribing. In a study comparing benzodiazepine use in 16 U.S. RACFs before 1990 and again in 1993-1994, overall use declined non-significantly by only 3.6% (26.4% to 22.8%).<sup>412</sup>

The reduction in U.S. RACF antipsychotic prescribing was not long-lasting. In the mid-2000s, several studies indicated that rates of use were fast approaching pre-OBRA-87 levels once more.<sup>413,414</sup> In a retrospective analysis of national Medicare data from 2000 to 2001, 28% of beneficiaries in RACFs received a prescription for an antipsychotic, and less than half of the treated residents received these drugs in accordance with the NH prescribing guidelines.<sup>91</sup> When Castle *et al.* tracked antipsychotic use in U.S. RACFs from 1996 to 2006 using a combination of databases, they found that antipsychotic use increased from 16% to 26% ( $P < 0.05$ ) throughout this 10 year period (see Figure 13). In addition, Castle *et al.* tracked the use of other psychotropic agents, reporting non-significant increases in both anxiolytic (16% to 19%) and hypnotic use (5% to 7%) over the same time period. Notably, antidepressant use more than doubled during the observation period (22% to 47%,  $P < 0.05$ ).<sup>414</sup>

**Figure 13: Changes in antipsychotic prescribing in U.S. nursing homes between 1996 and 2006**



The recent significant rise in antipsychotic prescribing in U.S. RACFs has been attributed to the increased availability of atypical antipsychotics, with these newer antipsychotics largely replacing typical agents.<sup>91,413</sup> Atypical antipsychotics are theorised to be used more readily because they are perceived to have a better adverse effect profile than typical agents and there is also extensive unlicensed use of these newer agents.<sup>91</sup> In fact, Kamble *et al.* reported that over 85% of the atypical antipsychotic prescribing to residents was for ‘off-label’ use.<sup>415</sup> It should be noted though, that in the U.S. none of the antipsychotics are licenced for BPSD, thus all prescriptions for older persons with dementia are deemed ‘off label’.

### **8.1.3 Psychotropic prescribing in RACFs outside the U.S.**

Despite increased political and social awareness of high rates of psychotropic medication use in RACFs since the first prevalence studies in the 1980s, studies from Canada, Europe and Australia indicate that rates of psychotropic use in this setting continue to be high. A summary of various international and national psychotropic prevalence studies is shown in Table 25. It should be noted that the prevalence rates from studies in different countries cannot be directly compared to each other as research methodologies may differ and the resident case-mix often varies between countries. To facilitate international comparison, a recent study utilised the ‘Resident Assessment Instrument’ to perform a cross-national analysis of antipsychotic use in RACFs in five countries; Canada, Finland, Hong Kong, Switzerland and the U.S. The prevalence of antipsychotic use between countries ranged from 11% (Hong Kong), 27% (Canada and the U.S), 34% (Switzerland) and 38% (Finland).<sup>416</sup> The authors of this study found substantial variations in antipsychotic rates across the five study countries, but also noted a wide variation in prevalence between RACFs in each country.<sup>416</sup> Within Australian prevalence studies, there are considerable differences in rates of use between states, moreover, this variation is even found within the same city. To illustrate; the rate of antipsychotic use was 5% lower in Nishtala *et al*’s 2008 prevalence study than in Snowdon *et al*’s 2009 study; however, the rate of anxiolytic and hypnotic prescribing in the former study was substantially higher.<sup>87,417</sup>

**Table 25: RACF psychotropic prevalence rates in international and Australian studies (in bold)**

Main author	Year of data collection	Country/ location	Sample details		Antipsychotic prevalence (%)	Anxiolytic prevalence (%)	Hypnotic prevalence (%)	Benzodiazepine prevalence(%)†	Antidepressant prevalence (%)
			RACF (n)	Residents (n)					
Mann E <sup>418</sup>	2007	Austria	48	1844	45.9	22.2	13.3	31	36.8
Meyer G <sup>419</sup>	2005	Germany	30	2367	28.4	12.9	10.7		21.1
Tucker M <sup>420</sup>	2005	New Zealand	26	1053	23.7	6.5	17.3	12.4	30.6
Selbaek G <sup>17</sup>	2004	Norway	26	1163	23.2	24.2	29		38.3
Hosia-Randell H <sup>421</sup>	2003	Finland	20	1987	42.6	26.3	27.5		44.6
Alanen H <sup>422</sup>	2003	Finland	41	3867	39	32.8	33.2		41.5
Nijk R <sup>*423</sup>	2003	Holland	25	1322	37.4	15.7	14.9		27.4
Hagen B <sup>424</sup>	2002	Canada	24	2443	23.2			15.4	
Demsey O <sup>398</sup>	2000	England	7	47	36			8.5	25.5
Lovheim H <sup>88</sup>	2000	Sweden		4357	26.2	17.6	27.5		43.2
<b>Snowdon J<sup>417</sup></b>	<b>2009</b>	<b>Sydney</b>	<b>48</b>	<b>2465</b>	<b>28</b>	<b>4.7</b>	<b>11.1</b>		<b>25.6</b>
<b>Somers M<sup>*379</sup></b>	<b>2009</b>	<b>WA</b>	<b>36</b>	<b>351</b>	<b>33.3</b>	<b>21.1</b>	<b>27.6</b>		<b>48.1</b>
<b>Nishtala P<sup>397</sup></b>	<b>2008</b>	<b>Sydney</b>	<b>62</b>	<b>500</b>	<b>22.6</b>	<b>7.8</b>	<b>16.2</b>		<b>33</b>
<b>Snowdon J<sup>90</sup></b>	<b>2003</b>	<b>Sydney</b>	<b>51</b>	<b>3093</b>	<b>23.6</b>	<b>4.1</b>	<b>11.3</b>		<b>20.5</b>
<b>Roughead E<sup>425</sup></b>	<b>2003</b>	<b>Australia</b>		<b>16 126</b>	<b>19.1</b>			<b>32</b>	<b>35</b>
<b>Snowdon J<sup>395</sup></b>	<b>1998</b>	<b>Sydney</b>	<b>38</b>	<b>1975</b>	<b>22.6</b>	<b>6.2</b>	<b>17</b>		<b>16</b>
<b>Draper<sup>83</sup></b>	<b>1997</b>	<b>Sydney</b>	<b>11</b>	<b>647</b>	<b>21.3</b>	<b>23.1</b>	<b>8.5</b>		<b>19.8</b>
<b>Snowdon J<sup>38</sup></b>	<b>1993</b>	<b>Sydney</b>	<b>46</b>	<b>2414</b>	<b>27.4</b>	<b>8.6</b>	<b>26.6</b>		<b>15.6</b>

† Data on overall benzodiazepine prevalence is not provided in the majority of studies

\* These studies are conducted in a selected sample of RACF residents with dementia

Recent U.S. studies have found that rates of antipsychotic and anxiolytic/hypnotic use are increasing in RACFs. Studies in other countries suggest that while some prevalence rates are rising, others are falling. When a Finnish study tracked psychotropic use from 2001 to 2003 in a sample of 41 facilities they found that while anxiolytic use decreased slightly from 35% to 33%, hypnotic use decreased markedly from 41% to 33%. The prevalence of antipsychotic medication and antidepressant use among residents remained unchanged.<sup>422</sup> Yet, when a Swedish research group compared psychotropic prevalence in a large RACF sample in 1982, and then again in 2000, antipsychotic use had decreased dramatically from 38% to 26%. In contrast, anxiolytic use increased from 5% to 18%, hypnotic use increased from 9% to 28%, and antidepressant use increased from 7% to 43%, suggesting that antipsychotics had been substituted for other psychotropic agents.<sup>88</sup> These two Scandinavian studies provide evidence that changes in psychotropic rates vary from country to country and may reflect differences in health systems.

In terms of Australian use, Professor Snowdon has performed a series of five prevalence studies in the same area of Central Sydney from 1993 to 2009.<sup>38,90,395,417,426</sup> Over the 16 year interval the prevalence of anxiolytic and hypnotic use has fallen from 9% to 5% (anxiolytics) and from 22% to 11% (hypnotics). On the other hand, the use of antipsychotics declined from 27% (1993) to 23% (2003), but by 2009, levels had returned to 1993 rates (28%).<sup>38,90,395,417,426</sup> It is of interest to note that this psychotropic utilisation trend, of increasing antipsychotic use and decreasing benzodiazepine use, was also observed in studies comparing Government (Medicare Australia) prescribing data from 2002 to 2007.<sup>61,101</sup>

## **8.2 Inappropriate psychotropic prescribing**

High prevalence rates of psychotropic use do not necessarily indicate inappropriate prescribing. For instance, a high rate of antipsychotic use could indicate high rates of psychiatric morbidity. One RACF may have a greater proportion of residents with schizophrenia or extreme aggressive behaviour than other RACFs. High rates of benzodiazepine use might also be found in a RACF catering for residents with substance abuse disorders. Therefore, prevalence rates cannot be exclusively relied on to assess the quality of psychotropic prescribing.

It is important to assess if the medication prescribed could be ‘potentially inappropriate’. There are several definitions of what constitutes a ‘Potentially Inappropriate Medication’ (PIM). In its most basic definition, a medication is considered potentially inappropriate ‘*if the risk associated with its use exceeds its benefit*’.<sup>85</sup> Two types of criteria for PIM use have been created which allow facilities, researchers and surveyors to assess and monitor the quality of prescribing.<sup>427</sup>

- Implicit criteria such as the ‘Medication Appropriateness Index’ (MAI); a measure of prescribing appropriateness that assesses 10 elements of prescribing, including indication, dose, duration, duplication and cost.<sup>428</sup> Although comprehensive, implicit criteria involve clinical interpretation of individual case notes, are time consuming, require patient consent, and are considered unworkable for analysis of large samples.<sup>85,427</sup>
- Explicit criteria consist of a specific list of drugs, drug classes and other prescribing indicators and are usually derived from published reviews or expert consensus.<sup>427,428</sup> In general, explicit criteria are generally preferred by researchers as they are more efficient to use, they can be used for large samples and do not rely on medical documentation which is historically noted to be inaccurate.<sup>429</sup>

Many of the medications classified as PIMs are psychotropic medications. In terms of assessing RACFs for inappropriate psychotropic prescribing, most researchers have adapted applicable criteria from either the Beers criteria or the U.S. RACF interpretive guidelines criteria.<sup>85</sup> Other explicit criteria to classify PIMs have also been developed, including the ‘Australian Prescribing Indicators’, the Canadian ‘Improving Prescribing in the Elderly Tool’ and the British ‘Screening Tool of Older Persons Prescriptions’.<sup>430-432</sup> Although each of these criteria has its own advantages and disadvantages, they are not commonly used, so do not facilitate comparison with other studies.

### **8.2.1 Beers Criteria**

The first explicit criteria for assessing for PIM prescribing in older people was published by Beers *et al.* in 1991<sup>433</sup> (Table 26). These criteria were originally designed for use in RACFs and were arrived at after a consensus process involving recognised experts.<sup>434</sup> There are several versions of the Beers criteria; the latest which was published in 2003, and consists of PIMs that should be avoided, doses that should not be exceeded and PIMs to avoid in specific medical conditions.<sup>359</sup> The Beers criteria is the most widely adopted criterion to assess for PIM prescribing, and as such, offers the advantage of enabling international comparison.<sup>435</sup> However, the Beers Criteria has several limitations. Firstly, many listed PIMs are not available outside the U.S. and some specific inappropriate psychotropic PIMs (e.g. nitrazepam,) are not included. Furthermore, the Beers criteria categorises some medications as ‘to be avoided’ that still have a role in treating older people, including amitriptyline, which is utilised successfully in older people to treat neuropathic pain. In addition, the Beers Criteria does not include drug duplication or drug-drug interactions. Finally, the criteria is not updated regularly so that it can lack relevance to current practice.<sup>427</sup>

**Table 26: Potentially inappropriate psychotropic medications for older people, regardless of diagnosis, based on the criteria of Beers.<sup>85</sup>**

<b>Antidepressants</b>
Amitriptyline
Doxepin
Fluoxetine
<b>Hypnotics</b>
Flurazepam
Temazepam > 15mg*
Zolpidem > 5mg*
<b>Anxiolytics</b>
Diazepam
Chlordiazepoxide
Oxazepam > 60mg*
Alprazolam > 2mg*
Lorazepam > 3mg*

\*Total daily dose

### 8.2.2 U.S. RACF Interpretive Guidelines

When the OBRA-87 legislation came into effect, prescribing ‘guidelines for long-term care facilities’ were promulgated, the latest iteration of which was published by Medicare and Medicaid in 2006 (Table 27).<sup>409</sup> These guidelines have several advantages, specifically they set a maximum effective dose for all psychotropic agents, specify indications and mandate standards for review, whereas the Beers criteria does not include such comprehensive indicators of prescribing quality relating to psychotropic use.<sup>359</sup>

**Table 27: Criteria for appropriate use of psychotropics according to the Centers for Medicare and Medicaid Services, interpretive guidelines for long term care facilities.<sup>409</sup>**

<b>Criteria</b>
<b>Antipsychotics</b>
One of ten specific conditions (e.g. schizophrenia)
For BPSD if symptoms are due to psychosis, the resident is a danger to self or others, the symptoms cause distress or impairs functional capacity
Daily doses for BPSD do not exceed: chlorpromazine (75mg), haloperidol (2mg), trifluoperazine (8mg), aripiprazole (10mg), olanzapine (7.5mg), quetiapine (150mg), risperidone (2mg)
<b>Anxiolytics</b>
One of seven specific conditions (e.g. GAD)
Daily doses do not exceed: flurazepam (15mg), chlordiazepoxide (20mg), diazepam (5mg), clonazepam (1.5mg), alprazolam (0.75mg), oxazepam (30mg), lorazepam (2mg)
<b>Hypnotics</b>
Daily doses do not exceed: flurazepam (15mg), lorazepam (1mg), oxazepam (15mg), temazepam (15mg), nitrazepam (5mg), zolpidem (6.25mg), zopiclone (5mg)



### **8.2.3 RACF incidence of Potentially Inappropriate Psychotropic Prescribing**

Beers *et al.* was the first to assess the degree of PIM prescribing in RACFs in 1991, applying their own criteria in a study of 12 facilities in Los Angeles. Forty per cent of prescribing was classified as inappropriate using their Beers criteria, with long acting benzodiazepines cited as the most common PIM.<sup>436</sup> Canadian researchers noted a significantly lower PIM incidence (21%) in a study conducted in the later 1990s, with TCAs (6%) and long acting benzodiazepines (6%) listed as the most common PIMs.<sup>437</sup>

In their seminal study, Briesacher *et al.* investigated potentially inappropriate antipsychotic prescribing in a sample of 1096 U.S. RACF residents, weighted to represent 2.5 million residents nationwide, during 2000-2001. Of a total of 28% of residents taking antipsychotics, more than half of these medications were prescribed inappropriately according to the long-term care facility interpretative guidelines. Nearly a quarter of residents taking antipsychotics had an inappropriate indication for use and 17% were taking doses that exceeded recommended maximum daily geriatric levels.<sup>91</sup> In the U.K, Osborne *et al.* modified the U.S. interpretative guidelines so they could assess potentially inappropriate psychotropic use in a random sample of 22 RACFs. They reported that out of all the residents taking antipsychotics, only 18% were using these agents appropriately.<sup>438</sup> Likewise, 93% of residents taking benzodiazepines were taking them inappropriately; notably, only 8% of users had a documented attempt at dose reduction in their RACF medical notes.<sup>439</sup>

Several studies have assessed PIM levels in Australian RACFs using the 2003 Beers criteria.<sup>379,440,441</sup> When King and Roberts applied the criteria to a sample of 998 residents from 15 RACFs in Queensland and NSW they observed that 6% and 3% of residents were taking the PIMs diazepam and amitriptyline, respectively.<sup>440</sup> Stafford *et al.* applied the Beers criteria to prescribing data from 41 Tasmanian RACFs in 2006, reporting that 6% of residents were taking the PIM amitriptyline and 6% were administered excessive doses of temazepam.<sup>441</sup> In a recent Western Australian study, conducted in a sample of residents with dementia from 36 RACFs, the most common PIMs were benzodiazepines, however no specific prevalence data was provided.<sup>379</sup> There are no known studies to have applied the OBRA-87-based interpretative guidelines to assess potentially inappropriate antipsychotic use in Australian RACFs.

### **8.3 Assessment of multiple psychotropic use**

Research has shown that the risk of falls and other adverse effects increases with the number and dosage of psychotropic drugs.<sup>81</sup> Hence, another approach to evaluate the quality of psychotropic prescribing is to quantify the cumulative effect of taking several medications with sedative properties. In practice, however, defining the effect of taking multiple sedative drugs is complex because different medication classes have different pharmacological effects and

consensus is lacking about how to best quantify sedative drug use.<sup>442</sup> There are three leading models that have been used to assess the effect of taking multiple sedative medications; the ‘Sedative Load’ model, the ‘Drug Burden Index’ (DBI) and the more recent addition, the ‘CNS Drug’ model.<sup>60,81,443</sup> The three models are outlined as follows:

### **8.3.1 The Sedative Load model**

This model was published in 2003 and developed by a group of researchers in Finland by classifying drugs by their sedative potential using a professional consensus approach. Drugs are divided into 4 groups which were: (1) primary sedatives; (2) drugs with sedation as a prominent side effect; (3) drugs with sedation as a probable side effect; and (4) drugs with no known sedation (see Table 28). Each medication in group 1 was assigned a sedative rating of 2, and each group 2 drug was assigned a rating of 1. Group 3 and 4 drugs were not assigned a rating. The ‘Sedative load’ is then calculated by adding the ratings for each drug a given person is taking.<sup>60</sup> The Sedative load has not, as yet, been applied to a RACF population but in a study conducted in 53 long-term geriatric care wards, 53% of patients were classified with having a ‘high sedative load’ and the most frequently used sedative drugs were benzodiazepines.<sup>444,445</sup>

### **8.3.2 The Drug Burden Index (DBI)**

The DBI was designed to serve as an evidence-based guide for prescribing in older people, and considers both anticholinergic and sedative drug burden. As the Index was developed using pharmacologic dose-response data, dosages of drugs are taken into account, unlike the Sedative Load model. The actual formula for the DBI is complex and is covered by an international patent:

$$\frac{E}{\alpha} = \frac{D}{\sum \delta + D}$$

Where  $E$  is the pharmacologic effect,  $\alpha$  is the proportionality constant,  $D$  is the daily dose, and  $\delta$  is the recommended minimum daily dose as approved by the U.S. Food and Drug Administration (FDA).<sup>442</sup> The DBI has been used retrospectively to evaluate the impact of pharmacist-led medication reviews in an Australian study utilising a random sample of 500 residents from 62 RACFs. The mean DBI score for residents decreased by 0.12 after their medications were reviewed and subsequently altered by GPs.<sup>446</sup>

**Table 28: List of medicines with a sedative effect for Sedative Load measures (in parenthesis: ATC code)<sup>60</sup>**

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<b>1. Primary sedatives</b>	<b>Examples of pharmacological substances</b>
<i>Traditional antipsychotics</i> (N05A)	phenothiazines, butyrophenones, thioxanthenes, sulpiride, lithium
<i>Anxiolytics</i> (N05B)	benzodiazepines, hydroxyzine
<i>Hypnotics and sedatives</i> (N05C)	benzodiazepines, zopiclone, zolpidem, zaleplon, valerian, clometiazole
<i>Antidepressants</i> (N06AA, N06C)	—clomipramine, trimipramine, nortriptyline, doxepin, amitriptyline —mianserin
<b>2. Drugs with sedation as a prominent side effect</b>	
<i>Alimentary</i> (A)	—propulsives, antiemetics metoclopramide, scopolamine
<i>Musculo-skeletal</i> (M)	—ibuprofen with codeine --- baclofen, tizanidine
<i>CNS</i> (N)	—opioids morphine, oxycodone, codeine, buprenorphine, tramadol, fentanyl —antiepileptics hydantoin derivatives, carbamazepine and derivatives, valproic acid, —anticholinergic anti-parkinson drugs gabapentin biperiden — <i>atypical antipsychotics</i> clozapine, olanzapine, quetiapine, risperidone —SSRI fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram —other antidepressants of second generation trazodone, nefazodone, mirtazapine, venlafaxine, milnacipran —drugs for migraine, incl. psychotropics meprobamate with ergot alkaloid, metoclopramide with ASA, triptans
<i>Respiratory</i> (R)	—old antihistamines —xanthines theophylline and its combinations —antitussives with sedating components bromhexine, ethylmorphine, codeine —antiemetics or drugs for dizziness, incl. psychotropics cyclizine (with diazepam), meclozine
<i>Ophthalmologicals</i> (S)	—anticholinergic drops for eyes scopolamine

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### 8.3.3 CNS Drug model

Another model to quantify the effect of multiple sedative medications is the CNS drug model, which categorises CNS drugs into four groups; antipsychotics, antidepressants, opioids and benzodiazepine receptor agonists. A CNS Standardised Daily Dose (*SDD*) is calculated by using the formula:

$$SDD = \frac{D}{MED}$$

Where the mean daily dose (*D*) of a CNS drug is converted to a *SDD* by dividing it with the minimum effective dose (*MED*) per day as per the U.S. Geriatric Dosage Handbook.<sup>447</sup> The total ‘CNS standardised daily dose’ is the sum of all the *SDDs*.<sup>81</sup> Although this formula is simple to

use and offers considerable potential, to date, the CNS drug model has not been utilised to date to assess CNS exposure in the residential aged care setting.

### **8.3.4 The application of multiple sedative assessment tools**

Like the methods to determine the extent of 'PIM' prescribing, each of the three models assessing multiple use of sedative agents have their own advantages and disadvantages. The Sedative Load model does not incorporate drug dosage, a factor which has been shown to impact falls and cognitive impairment.<sup>81,143</sup> Another rather odd disparity is that, contrary to clinical evidence, atypical antipsychotics are not classified as primary sedative agents but, instead as agents with a sedative effect. As such, these agents are only allocated a sedative rating of '1'. In effect, this means that a large dose of an atypical antipsychotic such as quetiapine, which is acknowledged as being highly sedating, is allocated the same score as a small dose of a combined analgesic, for example, paracetamol/codeine, which would have minimal sedative effects. The DBI, on the other hand, is complex to use and use is restricted because values such as the proportionality constant are not readily available. Analysis using the DBI would be time consuming when analysing large samples of patients. The CNS drug model is simpler in that it only includes opioids and psychotropic medication; however, the model treats medications such as SSRIs, medications known to cause insomnia, as being equivalent in terms of sedation potential, to drugs such as benzodiazepines and TCAs. It is also important to recognise that each multiple sedative use model has recently been developed recently and none have been utilised in the RACF setting, subsequently, they need validation and refinement.<sup>442</sup>

## **8.4 Aims and Objectives**

The aim of the first stage of this thesis was to determine current Tasmanian RACF psychotropic use and compare this to previous Tasmanian studies, and studies conducted nationally and abroad. Aside from obtaining an update on the prevalence and pattern of psychotropic use in Tasmanian RACFs, other key aims were to assess the appropriateness of prescribing, to identify determinants of Tasmanian psychotropic use, to determine the extent of use of multiple psychotropic agents, and finally, to assess the review of psychotropic medication.

This first stage of the thesis has been divided into two separate research studies. The first study aimed to assess the pattern and appropriateness of psychotropic use in Tasmanian RACFs and is outlined in chapters 9 to 11. The second study aimed to assess the review of psychotropic medication in the same sample of RACFs and is described in chapters 12 to 14. The key objective of stage one was to identify the principal patterns of use and review of psychotropic prescribing in Tasmanian RACFs so these could be subsequently targeted for the intervention project.

## CHAPTER NINE: METHODS

### ASSESSING PSYCHOTROPIC USE IN TASMANIAN RACFS

#### **9.1 Study design**

The first study of stage one was a retrospective cross-sectional study of prescribing data in a large representative sample of RACFs throughout Tasmania.

#### **9.2 Data Collection**

##### **9.2.1 Setting**

Tasmania is an Australian island and state, 240 kilometers south of the main continent. The state has a population of approximately 500 000, of whom almost half reside in the south in the vicinity of the capital city, Hobart. The state is often grouped into three main regions which are 'the South', 'the North' which is sighted around the city of Launceston, and 'the Northwest', in which the cities, Burnie and Devonport are located.<sup>56</sup> At the time of this study there were approximately 4300 residents in Tasmania living in 80 RACFs throughout the state.<sup>448,449</sup>

##### **9.2.2 Data collection**

In Australian RACFs, an accredited pharmacist completes an annual RMMR for each resident.<sup>50</sup> A group of three accredited pharmacists in Hobart are contracted to perform RMMRs for 40 RACFs in Tasmania; a sample comprising over half the facilities in the state. From November 2005 to January 2007, an annual RMMR was conducted for all residents residing at 40 facilities. RMMRs at each facility were conducted over several consecutive days. Whenever RMMRs were conducted by these pharmacists, case-note summaries were prepared using available data from medical records and medication charts at the RACF. Each case-note was coded with a unique identifier and information was entered into a Microsoft Access relational database. The case-note database represented a sample of just over half the RACF residents in Tasmania.

The information extracted from the case notes included demographic details such as the age, gender and mental health diagnoses of each resident. Individual antipsychotic, anxiolytic/hypnotic and antidepressant medications, usage rates and dosages at the time of review were also documented. All psychotropic medications taken by each resident were entered into the Access database. Medications taken on a 'prn', or 'as required' basis, were only categorised as 'regular' and recorded if they were taken regularly four or more days a week over the month prior to case-note collection. This definition of 'regular' medication use was chosen as it was considered that residents were taking the psychotropic medication more than half the

days of the week. Resident data was excluded from analysis if the resident was ‘temporary’ or ‘respite’, or if the case-note history in terms of demographic or medication data was incomplete.

### **9.2.3 Resident variables**

Included residents were classified into gender (male or female) and were separated into four distinct age range categories. The age categories were: <75 years, 75 – 84 years, 85 – 94 years and > 95 years. Specific mental health diagnoses were recorded when available. Variables, including the length of stay and overall number of medications taken by each resident, were not collected by the accredited pharmacists so were not included in the analysis.

### **9.2.4 RACF variables**

The details of all the RACFs were also recorded, including locality, rural status and number of residents. Accordingly, each facility was grouped into one of the three Tasmanian areas: ‘South’, ‘North’ and ‘North-west’ according to their location. Each facility was also classified as being situated in a ‘rural’, ‘semi-rural’ or ‘urban’ area using the ‘Pharmacy Access/Remoteness Index of Australia 2006/07’ (PhARIA).<sup>450</sup> PhARIA is an index used for the purpose of the pharmacy location rules to identify whether a locality is classified as urban or rural.<sup>450</sup> RACFs located in a PhARIA 1 area were categorised as ‘rural’, facilities located in PhARIA 2 were categorised as ‘semi-rural’ with all remaining facilities classified as ‘rural’. Finally, RACFs were classified into three groupings according to facility size: small (< 35 residents), medium (between 35-70 residents) and large (> 70 residents).

### **9.2.5 Pattern and appropriateness of psychotropic use**

The overall prevalence of psychotropic prescribing was expressed as percentages of residents taking psychotropic medications out of the total sample of residents. Psychotropic prevalence was also calculated at the RACF level in order to determine variation between facilities and facility variables.

The appropriateness of psychotropic use was assessed by a combination of two criteria. Firstly, as the Beers criteria is the most commonly used method in identifying potentially inappropriate prescribing in older people across countries, the criteria specifically relating to PIM medications, regardless of diagnosis, were applied to the Tasmanian RACF prescribing data. These criteria were taken from the latest Beers 2003 revision (refer to Table 26).<sup>359</sup> The recent Australian criteria were not applied as this would not permit comparison between other studies, both nationally and abroad.<sup>430</sup>

As the Beers criteria does not provide an indication of the appropriateness of antipsychotic prescribing, or offer comprehensive geriatric psychotropic dosing

recommendations, the criteria for appropriate psychotropic medication use according to the 'Centers for Medicare and Medicaid Services, interpretive guidelines for long term care facilities' were also applied to the Tasmanian RACF dataset (refer to Table 27).<sup>409</sup>

To obtain a measure of the extent of multiple psychotropic agent use, simple prevalence counts were also performed and recorded. None of the currently available 'multiple sedative agent' models, including the 'Sedative Load' model and the 'DBI', were utilised as they all have limitations as previously discussed in chapter 8 and they also all require extensive data on medications other than psychotropic medication, information which was not collected in the present study.<sup>60,409</sup> In addition, none of the current 'multiple sedative agent' models have been validated for use in the RACF setting.<sup>442</sup>

### **9.3 Statistical analysis**

All statistical analyses were performed using GraphAD InStat® version 2.04a. (GraphPad Software, San Diego, C, USA) and StatView®, version 5.0.1 (SAS Institute Inc, Cary NC, USA). Categorical variables between groups were analysed using chi-square analysis ( $\chi^2$ ). The Fishers Exact Test was used when at least one of the variables had less than five residents or values. The Mann-Whitney test was applied to compare non-parametrically distributed variables across groups. Simple bivariate statistical analysis was also performed where the proportions of residents taking psychotropics from different research studies were compared and analysed using chi-square analysis. 'P' values of 0.05 or less were considered statistically significant.

### **9.4 Ethical approval**

Approval for this data collection was granted by the Tasmania Social Sciences Human Research Ethics Committee.

## CHAPTER TEN: RESULTS

### ASSESSING PSYCHOTROPIC USE IN TASMANIAN RACFS

#### **10.1 Baseline data collection**

##### **10.1.1 Resident characteristics**

A total of 2 389 residents (74.8% female and 25.2% male) in 40 RACFs received a medication review and their case-notes were included in the study. The mean age of the residents was 84.5 years (S.D. 8.6), with the mean age of the women calculated as 85.5 years (S.D. 7.9) and of the men, 81.5 years (S.D. 9.8). A small proportion of the residents, 235 (9.8%) were younger than 75 years, 774 (32.4%) were aged between 75 and 84 years, 1 159 (48.5%) were aged between 85 and 94 years, and 221 (9.2%) were over 95 years of age.

The incidence of recorded mental health diagnoses among residents was as follows: 1 070 (45%) of residents were diagnosed with dementia or 'short term memory loss/cognitive impairment'. A total of 84 (3.5%) residents were diagnosed with anxiety and 45 (2%) had a diagnosis of schizophrenia. Only ten of the residents had a recorded diagnosis of insomnia.

##### **10.1.2 RACF characteristics**

The size of the RACFs varied from 19 to 152 beds, with a mean size of 60 beds. In terms of RACF size, 14 facilities were categorised as 'large', 12 facilities as 'medium' and 14 facilities as 'small'. Twenty facilities with 1 394 residents (58%) were located in the south, fourteen RACFs comprising 731 residents (31%), were situated in the north. The remaining six RACFs, with 264 residents (11%) were located in the north-west region of the state. In terms of rural status, twenty seven of the RACFs were classified as 'urban', with 1 838 residents (77%) residing in these facilities. Three RACFs were classified as 'semi-rural', comprising of 222 residents (9%); and ten facilities were classified as 'rural' having a total of 329 residents (14%). The baseline characteristics of the RACFs in each of the three regions are displayed in Table 29.

The RACFs in the northwest region of Tasmania had a slightly higher proportion of female residents and had fewer residents than RACFs in the Southern and Northern regions. However, the only statistically significant difference between the facilities in each region was in rural status. Considerably fewer Southern RACFs (10%) and Northern RACFs (29%) were categorised as rural, whereas two thirds of all north-western facilities were rural.



**Table 29: Baseline characteristics of the three Tasmanian regions**

<b>Characteristic</b>	<b>South N (%)</b>	<b>North N (%)</b>	<b>North-West N (%)</b>	<b>total N (%)</b>	<b>P</b>
Number of RACFs	20 (50)	14 (35)	6 (15)	40 (100)	
Number of residents	1394 (58)	731 (31)	264 (11)	2389 (100)	
Number of females	1047 (75)	535 (73)	205 (78)	841 (100)	0.3
Number of RACFs with < 35 residents	6 (30)	4 (29)	4 (67)	14 (100)	0.2
Number of RACFs with > 71 residents	10 (50)	3 (22)	1 (17)	14 (100)	0.1
Number of RACFs classified as 'rural'	2 (10)	4 (29)	4 (67)	10 (100)	<b>&lt; 0.02</b>

## **10.2 Psychotropic prevalence**

A total of 1 596 residents, just over two thirds of the residents (66.8%) in the 40 RACFs, were regularly taking at least one psychotropic medication. A fifth of the residents were taking antipsychotics (21.7%), 42.8% were taking anxiolytics/hypnotic agents and 35.2% were taking antidepressants on a regular basis. Table 30 provides specific details of the psychotropic medications used and also provides a breakdown of the proportions of residents taking typical and atypical antipsychotics, hypnotics, anxiolytics and antidepressants from different classes. The use of 'prn' psychotropic medication was minimal, accounting for a very small proportion of psychotropic use. In Tasmanian RACFs specific administrative procedures are required before 'prn' drugs are given so many of these drugs are transferred over to the 'regular chart' to facilitate easier access.

**Table 30: Number (%) of RACF residents taking psychotropic medication regularly from Nov 2005 to Jan 2007\***

<i>Psychotropic</i>	(n=2 389)
<b>Any psychotropic</b>	<b>1596 (67%)</b>
<b>Antipsychotics</b>	<b>502 (21%)</b>
<u>Typical</u>	171 (7%)
Haloperidol	108
Chlorpromazine	28
Thioridazine	3
<u>Atypical</u>	348 (15%)
Risperidone	201
Olanzapine	131
Quetiapine	13
<b>Anxiolytic/hypnotics</b>	<b>1024 (43%)</b>
<u>Hypnotics</u>	677 (27.5%)
Temazepam	595
Nitrazepam	54
Zopiclone	10
Zolpidem	9
<u>Anxiolytics</u>	494 (21%)
Oxazepam	268
Diazepam	166
Alprazolam	53
<b>Antidepressants</b>	<b>841 (35%)</b>
<b>Tricyclics</b>	211 (9%)
<b>SSRIs</b>	446 (19%)
Mirtazapine	104 (4%)
Venlafaxine	73 (3%)
Moclobemide	24 (1%)
Mianserin	3

\* NB. Many residents were taking multiple psychotropic agents

### 10.2.1 Pattern of psychotropic use by gender

Table 31 displays the psychotropic categories according to resident gender. The psychotropic groups are further broken down into atypical and typical antipsychotics, anxiolytic and hypnotic agents and different antidepressant classes. There were several statistically significant differences between the proportions of males and females taking different types of psychotropic medication. Female residents were more likely to take a psychotropic medication than males ( $\chi^2 = 4.5$ ,  $df = 1$ ,  $P < 0.05$ ). Likewise, females were more likely to take antidepressants ( $\chi^2 = 6.5$ ,  $df = 1$ ,  $P < 0.01$ ). However, when antidepressant use was broken down further there was no significant difference between the proportion of males and females taking SSRIs and other antidepressants. There were, however, significantly more females taking TCAs ( $\chi^2 = 6.7$ ,  $df = 1$ ,  $P < 0.01$ ). There was no difference between genders in terms of overall antipsychotic and atypical antipsychotic use. The only category where males were more likely to take psychotropic medication was in typical antipsychotic use ( $\chi^2 = 6.8$ ,  $df = 1$ ,  $P < 0.01$ ).

**Table 31: Psychotropic use according to resident gender**

Category	Female (n = 1787) N (%)	Male (n = 602) N (%)	Total (n=2389) N (%)	P
<b>Any psychotropic</b>	1215 (68)	381 (63)	1596 (67)	<b>&lt;0.05*</b>
<b>antipsychotic</b>	359 (20)	143 (24)	502 (21)	0.06
atypical antipsychotic	255 (14)	93 (15)	348 (15)	0.46
typical antipsychotic	116 (7)	55 (9)	171 (7)	<b>&lt;0.01*</b>
<b>antidepressant</b>	655 (37)	186 (30)	841 (35)	<b>&lt;0.01*</b>
SSRIs + others	497 (28)	155 (26)	652 (27)	0.32
Tricyclics	174 (10)	37 (6)	211 (9)	<b>&lt;0.01*</b>
<b>Anxiolytic/hypnotics</b>	789 (44)	235 (39)	1024 (43)	<b>&lt;0.005*</b>
anxiolytics	391 (22)	99 (16)	494 (21)	<b>&lt;0.005*</b>
hypnotics	513 (29)	164 (27)	677 (28)	0.13

The most marked difference in psychotropic use between females and males occurred in the anxiolytic/hypnotic category. Females were significantly more likely to take these agents ( $\chi^2 = 8.5$ ,  $df = 1$ ,  $P < 0.005$ ) than males. When this use was examined in detail, it was found that females were significantly more likely to take anxiolytic benzodiazepines ( $\chi^2 = 8.4$ ,  $df = 1$ ,  $P < 0.005$ ), but there was no significant difference between the proportion of males and females taking hypnotic medications ( $\chi^2 = 2.3$ ,  $df = 1$ ,  $P = 0.13$ ).

### 10.2.2 Pattern of psychotropic use by age

The same categories were used to determine differences in psychotropic use according to resident age group (Table 32). The likelihood of taking any psychotropic agent significantly decreased with increasing age ( $\chi^2 = 15.9$ ,  $df = 3$ ,  $P < 0.005$ ). This trend of decreasing use was particularly marked in the use of antipsychotics ( $\chi^2 = 41.4$ ,  $df = 3$ ,  $P < 0.0001$ ) and antidepressants ( $\chi^2 = 30.3$ ,  $df = 3$ ,  $P < 0.0001$ ). It should be noted, however, that age did not significantly influence the pattern of TCA use ( $\chi^2 = 0.7$ ,  $df = 3$ ,  $P = 0.9$ ) or the use of anxiolytic/hypnotic medication ( $\chi^2 = 1.6$ ,  $df = 3$ ,  $P = 0.7$ ).

**Table 32: Psychotropic use according to resident age group**

Category	<75 (n = 235) N (%)	75-84 (n = 774) N (%)	85-94 (n = 1 159) N (%)	>95 (n = 221) N (%)	Total (n=2 389) N (%)	P
<b>Any psychotropic</b>	168 (71)	544 (70)	749 (65)	135 (61)	1 596 (67)	<b>&lt;0.005*</b>
<b>antipsychotic</b>	73 (31)	200 (26)	192 (17)	37 (16)	502 (21)	<b>&lt;0.0001*</b>
atypical antipsychotic	52 (22)	147 (19)	125 (11)	24 (10)	348 (15)	<b>&lt;0.0001*</b>
typical antipsychotic	29 (13)	58 (8)	72 (6)	12 (6)	171 (7)	<b>&lt;0.005*</b>
<b>antidepressant</b>	93 (40)	319 (41)	376 (32)	53 (24)	841 (35)	<b>&lt;0.0001*</b>
SSRIs + others	76 (33)	248 (32)	286 (25)	32 (15)	652 (27)	<b>&lt;0.0001*</b>
Tricyclics	18 (8)	70 (9)	99 (9)	20 (9)	211 (9)	0.86
<b>anxiolytic/hypnotics</b>	105 (45)	321 (41)	507 (43)	91 (41)	1 024 (42)	0.67
anxiolytics	58 (25)	156 (20)	238 (20)	42 (19)	494 (21)	0.15
hypnotics	62 (26)	225 (29)	323 (28)	56 (25)	666 (28)	0.87

### 10.3 RACF psychotropic pattern of use

There was wide inter-facility variation in the proportion of residents taking psychotropic medication. The use of one or more psychotropic agents in each RACF ranged from 51% to 89% of residents (Mean: 67.4%; SD 9.0). Anxiolytic/hypnotic use between facilities ranged from 29% to 63% (Mean: 44.3%; SD 8.8) and antidepressant use in each facility ranged from 15% to 58% of residents (Mean: 35.4%; SD 9.8). Notably, the greatest variation in psychotropic use was observed in antipsychotic usage which ranged from 3.5% to 57.0% of residents (Mean: 20.3%; SD 10.7).

#### 10.3.1 Prevalence of psychotropic use by RACF size

Table 33 displays the psychotropic categories according to RACF size. For these facility analyses, psychotropic categories were not further broken down further into variables such as typical or atypical antipsychotics.

**Table 33: Psychotropic use according to RACF size**

Category	Large (n = 1 355) N (%)	Medium (n = 647) N (%)	small (n = 387) N (%)	total (n=2 389) N (%)	P
<b>Any psychotropic</b>	892 (66)	444 (69)	261 (67)	1 596 (67)	0.4
<b>antipsychotic</b>	291 (21)	138 (21)	73 (19)	502 (21)	0.5
<b>antidepressant</b>	480 (35)	229 (35)	132 (34)	841 (35)	0.9
<b>anxiolytic/hypnotics</b>	557 (41)	281 (43)	186 (48)	1 024 (42)	< 0.05*

The size of the facility did not influence total psychotropic, antipsychotic or antidepressant use. However, residents residing in RACFs with fewer beds were significantly more likely to use anxiolytic/hypnotic agents than residents living in larger facilities ( $\chi^2 = 6.1$ ,  $df = 2$ ,  $P < 0.05$ ).

### 10.3.2 Prevalence of psychotropic use by RACF locality

Table 34 displays the psychotropic categories according to the locality of the RACFs.

**Table 34: Psychotropic use according to RACF locality**

Category	South (n = 1 394) N (%)	North (n = 731) N (%)	North-West (n = 264) N (%)	total (n=2 389) N (%)	P
<b>Any psychotropic</b>	919 (66)	491 (67)	186 (70)	1 596 (67)	0.4
<b>antipsychotic</b>	301 (22)	143 (20)	58 (22)	502 (21)	0.5
<b>antidepressant</b>	479 (34)	269 (37)	93 (35)	841 (35)	0.5
<b>anxiolytic/hypnotics</b>	590 (42)	302 (41)	132 (50)	1 024 (42)	< 0.05*

Locality did not influence RACF use of any psychotropic agent, antipsychotics or antidepressants. In contrast, the use of anxiolytic/hypnotic medication in North-West RACFs was significantly higher than in the Southern and Northern regions ( $\chi^2 = 6.4$ ,  $df = 2$ ,  $P < 0.05$ ).

### 10.3.3 Prevalence of psychotropic use by rural classification of RACF

Table 35 shows the psychotropic categories according to the rural classification (as per PhARIA) of the RACFs. None of the categories of psychotropic use was influenced significantly by the rural classification of the RACF.

**Table 35: Psychotropic use according to rural classification**

Category	Urban (n = 1 838) N (%)	Semi-rural (n = 222) N (%)	Rural (n = 329) N (%)	Total (n=2 389) N (%)	P
<b>Any psychotropic</b>	1 215 (66)	153 (69)	228 (69)	1 596 (67)	0.4
<b>antipsychotic</b>	389 (21)	43 (19)	70 (21)	502 (21)	0.8
<b>antidepressant</b>	631 (34)	84 (38)	126 (38)	841 (35)	0.3
<b>anxiolytic/hypnotics</b>	769 (42)	104 (47)	151 (46)	1 024 (42)	0.18

#### **10.4 Prevalence of potentially inappropriate psychotropic prescribing**

##### **10.4.1 Prevalence of potentially inappropriate psychotropic prescribing according to Beers criteria**

The number and proportion of residents fulfilling at least one potentially inappropriate psychotropic medication as determined by the Beers Criteria are listed in Table 36

**Table 36: Potentially inappropriate psychotropic prescribing according to Beers Criteria**

	Number (%) of residents
<b>Antidepressants</b>	841 (35)
Amitriptyline	128 (5.4)
Doxepin	46 (1.9)
Fluoxetine	<u>37 (1.5)</u>
	211 (8.8)
<b>Hypnotics</b>	677 (27.5)
Flurazepam	0 (0)
Temazepam > 15mg*	138 (5.8)
Zolpidem > 5mg*	<u>9 (0.4)</u>
	147 (6.1)
<b>Anxiolytics</b>	494 (21)
Diazepam	166 (7.0)
Chlordiazepoxide	0 (0)
Oxazepam > 60mg*	17 (0.7)
Alprazolam > 2mg*	8 (0.4)
Lorazepam > 3mg*	<u>2 (&lt; 0.1)</u>
	193 (8.1)

\*Total daily dose

The main PIMs, as categorised by the Beers criteria, were diazepam, high dose temazepam and amitriptyline. According to this criterion, over a third of the anxiolytic benzodiazepine prescribing, a quarter of antidepressants and over a fifth of hypnotic agents prescribed were potentially inappropriate.

#### **10.4.2 Prevalence of potentially inappropriate psychotropic according to U.S. Long-term care facility interpretive guidelines**

The number and proportion of residents fulfilling at least one potentially inappropriate psychotropic medication as categorised by the U.S. long-term care facility interpretive guidelines are listed in Table 37

**Table 37: Potentially inappropriate psychotropic medication according to U. S. Long-term care facility interpretive guidelines**

<b>Criteria</b>	<b>Number (%) of residents</b>
<b>Antipsychotics</b>	<b>502 (21)</b>
Not for Specific conditions (e.g. schizophrenia) For BPSD but not meeting criteria	54 (2.3) – no mental health diagnosis NA
Daily doses for BPSD exceeding:	
chlorpromazine (75mg)	8 (0.3)
haloperidol (2mg)	17 (0.7)
trifluoperazine (8mg)	2 (< 0.1)
aripiprazole (10mg)	2 (< 0.1)
olanzapine (7.5mg)	14 (0.6)
quetiapine (150mg)	5 (0.2)
risperidone (2mg)	21 (0.9)
<b>Anxiolytics</b>	<b>494 (21)</b>
Not for of seven specific conditions (e.g. GAD)	355 (14.9)* – no mental health diagnosis
Daily doses exceeding:	
diazepam (5mg)	48 (2.0)
alprazolam (0.75mg)	23 (1.0)
oxazepam (30mg)	47 (2.0)
lorazepam (2mg)	5 (0.2)
<b>Hypnotics</b>	<b>677 (27.5)</b>
Daily doses exceeding:	
temazepam (15mg)	138 (5.8)
nitrazepam (5mg)	11 (0.5)
zolpidem (6.25mg)	9 (0.4)
zopiclone (5mg)	9 (0.4)

\* N.B. This figure represents total benzodiazepine use without a diagnosis

In this study it was not possible to complete several of the interpretive guideline criteria as the specific indication for antipsychotic and anxiolytic use was not annotated on the resident case notes. This information was required in order to assess if the indication for use was appropriate. Therefore, as an alternative, the number of residents prescribed antipsychotics and anxiolytic/hypnotics without a recorded mental health diagnosis was tallied to provide an 'absolute minimum figure' for this criterion. The main potentially inappropriate psychotropic

medication as categorised by the U.S. long-term care facility interpretive guidelines were anxiolytic/hypnotic use without a diagnosis (15% of residents), followed by the use of an antipsychotic agent without a diagnosis (2% of residents), and high-dose temazepam use.

According to the U.S. interpretive guideline criteria, over a third of all the residents' anxiolytic/hypnotic use was potentially inappropriate because these agents were used in the absence of a psychiatric diagnosis. Further, nearly a third, 29%, of the anxiolytic/hypnotic medications taken exceeded the recommended maximum geriatric daily dose. With regards to antipsychotic use, 11% of residents using antipsychotic medication did not have a recorded diagnosis of mental illness and over one in ten antipsychotic users were taking doses exceeding the recommended maximum geriatric daily dose.

### **10.5 Prevalence of multiple psychotropic use**

Table 38 lists the prevalence of multiple psychotropic agent use in the residents.

**Table 38: Prevalence of multiple psychotropic agent use**

<b>Category</b>	<b>total n= 2389 N (%)</b>
One or more psychotropics	1596 (67)
Two or more psychotropics	765 (32)
Three or more psychotropics	216 (9)
Benzodiazepine + antipsychotic	237 (10)
Two antipsychotic agents	16 (0.6)
Two benzodiazepine agents	129 (5.4)

When multiple psychotropic use was analysed, it was found that almost a third of all residents were taking two or more psychotropics, with approximately one in ten residents taking three or more psychotropic medications. Of note was the high number of residents taking antipsychotic and benzodiazepine medication concomitantly. In effect, this means that nearly half the residents taking antipsychotic agents were also taking a benzodiazepine. Although the use of combination antipsychotics (i.e. taking two or more antipsychotics at the same time) was quite minimal (< 1%), over 5% of residents were taking a combination of two benzodiazepines. This means that 13%, or one in seven residents taking benzodiazepines were taking two benzodiazepine agents at the same time.

Like single agent psychotropic use, there was a sizable variation among facilities in multiple psychotropic prescribing. The proportion of residents taking two or more psychotropic agents ranged from 17% to 53% among the 40 RACFs, with the proportion of residents taking three or more psychotropic medications ranging from nil to 26% of residents. Use of combination antipsychotic-benzodiazepine treatment ranged from nil to 28% of residents among the RACFs, and the proportions of residents taking two benzodiazepines concurrently ranged from 0 to 20%.



## CHAPTER ELEVEN: DISCUSSION

### ASSESSING PSYCHOTROPIC USE IN TASMANIAN RACFS

#### 11.1 Prevalence of psychotropic use

This study demonstrates that psychotropic medications are utilised extensively by residents of Tasmanian RACFs, with over two thirds of residents regularly taking at least one agent. Benzodiazepines were the most commonly used psychotropic class, with 42% of residents taking these medications. Over a quarter of residents were taking anxiolytic benzodiazepines, and one in five residents was taking a hypnotic agent on a regular basis, 97% of which were benzodiazepines. Less than twenty residents were taking the newer z-drugs, a finding which was not surprising given the fact that these newer hypnotic agents are not subsidised on the Australian PBS.<sup>102</sup>

The psychotropic prevalence data can be compared to that recorded in two other Tasmanian studies completed in the early 1990s.<sup>84,406</sup> It should be noted that this is a “loose” comparison as these cross-sectional studies were conducted in specific regions of the state and the sample of RACFs were much smaller than the present study. Munro *et al.*, for instance, conducted their study in a small group of 5 RACFs in the northwest of the state.<sup>84</sup> In spite of this limitation, it is important to note that the percentages of residents taking antipsychotic and hypnotic medications in these early studies were considerably higher than that found in this 2006 study. For example, Miller *et al.* reported an hypnotic prevalence rate of 59% in their study, whereas the hypnotic use in this 2006 study was 28%.<sup>406</sup> The apparent decline in the use of Tasmanian psychotropic medication over the last ten years could be due to a greater awareness of alternative management options for mental health conditions and/or a consequence of the introduction of pharmacist medication review services.

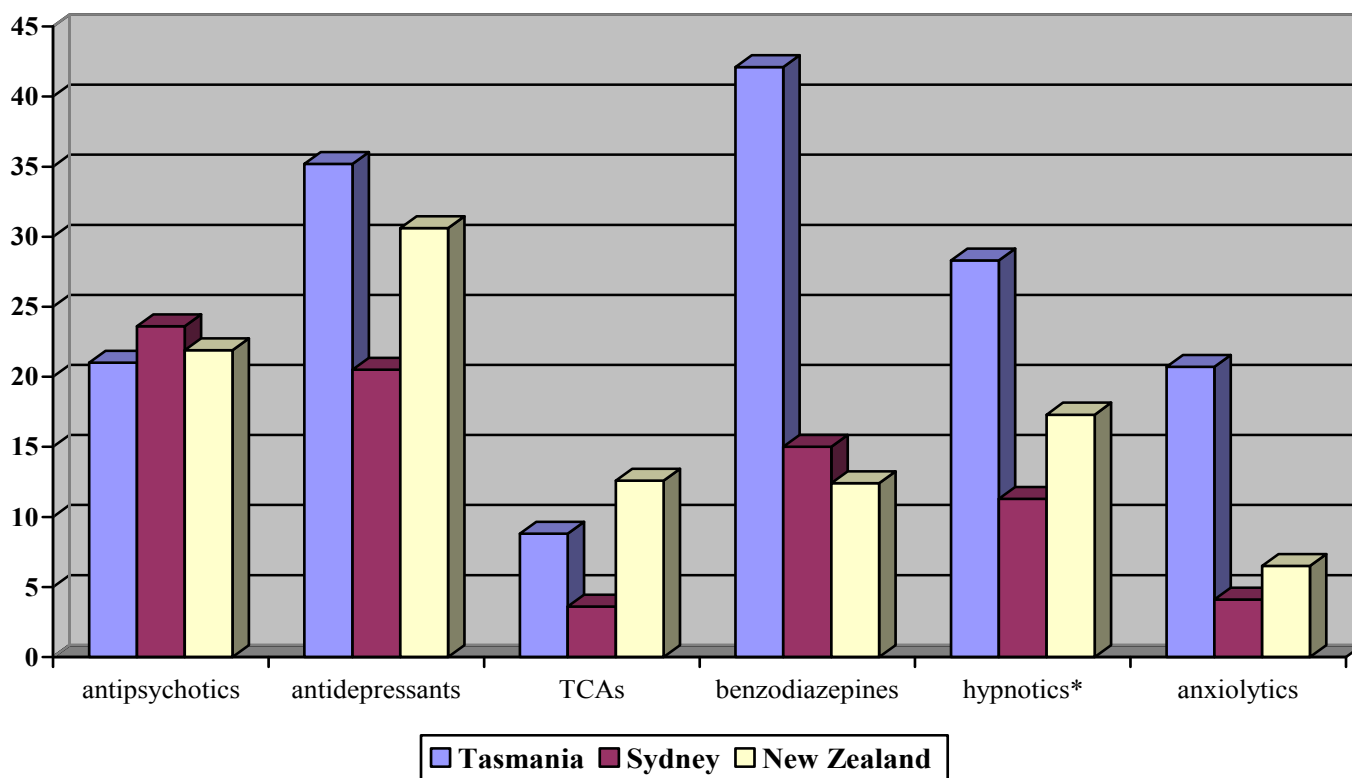
International comparisons of psychotropic use are problematic because of marked differences between countries in residential aged care structure, legislation controlling aged care services and in their resident case-mix. It is important to note, also, that factors such as methodology and definition of ‘regular’ prescribing may differ between studies, meaning that the results of different research studies are not directly comparable. It is useful, though, to compare and contrast the present Tasmanian psychotropic prevalence data to that collected from two other studies conducted in Australia and New Zealand within a similar time frame. In the first study, Snowden *et al.* investigated psychotropic prevalence in 51 Central Sydney RACFs during 2003.<sup>451</sup> The second study involved an audit of psychotropic use in 26 facilities in Hawkes Bay, New Zealand in 2005.<sup>451</sup> Although the three studies differ slightly in

methodology, a general comparison offers the opportunity to benchmark psychotropic use found in other areas in the same region, within same period of time.

When the three studies are compared to each other, significant differences in psychotropic use emerge (Figure 14). Firstly, the proportion of residents taking antipsychotics in Tasmania was 3% lower than Central Sydney and New Zealand, however, this difference only reached statistical significance in Central Sydney ( $\chi^2=5.2$ ;  $df=1$ ,  $P<0.02$ ), but not in New Zealand ( $\chi^2=3.0$ ;  $df=1$ ,  $P=0.08$ ).<sup>90,420</sup> Over a third of residents were taking older typical antipsychotic agents in both of the Australian studies, while in New Zealand, the figure was lower, with less than a quarter of RACF residents taking typical antipsychotics.<sup>90,420</sup> The use of typical antipsychotics appears to be considerably less in the U.S. where, according to the 2004 National RACF Survey, only 5% of all residents with dementia were taking ‘typical’ agents.<sup>452</sup>

Variation can also be seen in the pattern of antidepressant use between studies. The use of antidepressant agents in Tasmanian RACFs was significantly higher than in Central Sydney ( $\chi^2=147$ ;  $df=1$ ,  $P<0.0001$ ) and in New Zealand ( $\chi^2=7.0$ ;  $df=1$ ,  $P<0.01$ ).<sup>90,420</sup> It should be noted, though, that a large proportion of this use can be accounted for by TCA use, particularly in New Zealand, where 41% of the antidepressants used were TCAs.<sup>388</sup>

**Figure 14: Psychotropic prevalence studies in Australasia 2003-2006**



\* N.B. Hypnotic use includes the use of z-drugs

The major issue when the Tasmanian rates are compared to the rates found in other studies is the large difference between prevalence of benzodiazepine RACF use. The prevalence of 42% in this Tasmanian study was approximately triple that reported in Central Sydney (15%) and New Zealand (12%). The differences in prevalence rates of benzodiazepine usage between Tasmania and the other studies are very significant (Sydney:  $\chi^2=304$ ;  $df=1$ ,  $p<0.0001$ , and NZ:  $\chi^2=528$ ;  $df=1$ ,  $p<0.0001$ ). When use is broken down into anxiolytic and hypnotic rates of prescribing, it is evident that the largest difference in use occurs in anxiolytic prescribing (Figure 14). It is difficult to account for this finding, however an independent report released in 2008 highlighted that anxiolytic benzodiazepine dispensing rates across Tasmania, including the community setting, were 140-300% above the national average.<sup>453</sup> This high usage was also noted in the AIHW 2007/2008 report on mental health services, where Tasmanian health professionals, 97% of whom were GPs, prescribed a higher proportion of anxiolytics than the national average (21% compared with 15.6%).<sup>454</sup> Many residents are probably admitted to Tasmanian RACFs already taking benzodiazepines with a long history of use, making modification of therapy difficult. Another factor which may account for the large difference in the benzodiazepine usage rate is the relatively poor provision of psychogeriatric services in Tasmania. A state-by-state comparison of psychiatric services published in 2006 noted that Tasmania had Australia's third lowest psychiatrist support level and the lowest rate of allied health provision (e.g. psychologist, diversional therapist or social worker) for older people in Australia.<sup>455</sup> This lack of professional mental health support means that older Tasmanians in RACFs have limited access to counselling or other psychological therapies. Consequently, due to an absence of alternative treatment options, staff in Tasmanian RACFs may depend on pharmacological treatment strategies to a greater extent than RACFs elsewhere in Australia.

Another possible reason for the high use of benzodiazepines in Tasmanian RACFs is that these drugs are being prescribed routinely to manage behavioural and psychological symptoms associated with dementia, contrary to professional guidelines and the absence of a research base to support their use for this indication.<sup>95,96</sup> This proposition aligns with the observation that the rate of antipsychotic prescribing in this sample of Tasmanian RACFs was significantly lower than that found in Sydney and in many international studies.<sup>90,91,418,419,423</sup> RACFs may be using benzodiazepines as an alternative to antipsychotics. When a recent British study investigated prescribing patterns in 8 U.K. National Health Service 'trusts', it was found that benzodiazepines were the most frequently prescribed psychotropic agents to treat BPSD, making up 32% of the total volume of psychotropic prescribing.<sup>456</sup> The authors of this British study theorised that the reasons these agents were prescribed more frequently for this indication was because of their faster onset of action compared with other agents or due to their sedative properties.<sup>456</sup> Tasmanian prescribers may be using benzodiazepines for the same reasons;

however, as detailed information on diagnoses and indications for psychotropic medication was not available in the case-notes of residents, the specific reasons underlying benzodiazepine prescribing can only be speculative.

The rate of benzodiazepine use in Central Sydney RACFs has more than halved over the past ten years. This is probably due to several factors. To start, when Snowdon *et al*'s 1993 prevalence study was published in 1995 there was considerable media focus on the findings.<sup>39</sup> As a consequence, the NSW government released a series of guidelines for RACFs and GPs, promoting appropriate management of old age mental health conditions.<sup>242</sup> The combined effect of media and political attention, and guideline promotion, is likely to have contributed to the marked reduction in Central Sydney RACF benzodiazepine use over the past decade. Although data from several Tasmanian studies in the mid-nineties indicated that benzodiazepine use was actually higher in Tasmanian RACFs than in Central Sydney at the same time, there was little publicity focused on the findings and no government intervention to address the issue. It is significant to note that Tasmanian benzodiazepine usage rates do not appear to have altered as dramatically as Sydney's have over the past decade.

The rate of benzodiazepine use in Hawke's Bay, New Zealand has also 'substantially reduced' over the past 15 years.<sup>388</sup> Like in Sydney, Tucker *et al.* attributed the decline to significant media and political attention. In 2001, there was a highly publicised incident where benzodiazepine use triggered a violent attack by an older man. It is interesting to note that a larger proportion of hypnotic drugs in the New Zealand study are zolpidem or zopiclone, probably due to the fact that these drugs are subsidised by the New Zealand government. However, even taking this usage into account, the use of hypnotic agents was still substantially lower than that found in our Tasmanian study.<sup>388</sup>

## **11.2 Determinants of RACF psychotropic use**

One of the main observations in this cross-sectional study was the wide variation in psychotropic prescribing among the forty Tasmanian RACFs. This same variation has been observed in the majority of RACF psychotropic prescribing studies both in Australia and overseas.<sup>83,90,416,457,458</sup> Resident and facility characteristics have been evaluated as possible factors linked with psychotropic use. However, the associations found in different studies have not been consistent. One issue that is often raised is whether the resident case-mix within the RACF itself influences psychotropic rates of use. For instance, whether RACFs with a higher proportion of people with dementia would have a higher prevalence rate of psychotropic use than facilities with fewer residents with dementia? Research around this has been mixed with Queensland researchers arguing that psychotropic use in Hostels, a residential setting where residents require a low level of care, is often as high, or sometimes higher, than some high-care

RACFs.<sup>459</sup> The same research team reported that psychotropic use appeared to be linked to the ‘culture’ of the hostel, with less supportive hostels (e.g. less staff, fewer quality control processes) exhibiting higher rates of psychotropic use than more supportive hostels.<sup>459</sup> The association of case-mix with psychotropic prescribing quality and rates of use was not able to be tested in the present study as the precise resident case-mix with regards to mental health diagnoses in each RACF was difficult to determine due to the poor quality of diagnosis and medical record recording. Other researchers have reported the same limitations in RACF medical record keeping.<sup>15,460</sup>

In the current study, the use of one of more psychotropic medications was influenced by both the gender and age of the resident, with female and younger residents more likely to take psychotropic medication in general. This pattern was also observed by Draper *et al.* in a study conducted in 11 Sydney RACFs ten years earlier.<sup>83</sup> Yet, when psychotropic use was examined in closer detail, variations in associations with gender between studies were found. For instance, in the present study, there was no significant difference between males and females in atypical antipsychotic use, while males were significantly more likely to take typical antipsychotics. However, in several U.S. RACF studies, males were significantly more likely to be using any type of antipsychotic medication, whether atypical or typical.<sup>413,452,458</sup> The U.S. researchers attributed the higher use of antipsychotics to males displaying more severe and aggressive behavioural symptoms.<sup>413,458</sup> For some reason, prescribers in Tasmania are more willing to prescribe atypical antipsychotics than they are to prescribe typical antipsychotics to women. Perhaps this is due to the atypical antipsychotics’ perceived superior safety profile. Interestingly, a recent study of Australian PBS antipsychotic claim data noted the high proportion of older females taking the newer atypical antipsychotics outside approved indications, despite the need for authority prescriptions.<sup>101</sup>

Another observation in this study was that anxiolytic and antidepressant use was higher among women than in men. This is most probably an indication that women are twice as likely to suffer long term mood and anxiety disorders.<sup>461</sup> This association was also noted in several U.S. RACF studies; although, gender was not associated with anxiolytic use in a large Dutch study of residents with dementia.<sup>412,423,462</sup>

Younger residents were significantly more likely to be prescribed any psychotropic agent, an antipsychotic or an antidepressant. In contrast, there was no significant difference in the rate of anxiolytic/hypnotic prescribing between younger and older age groups. This observation accords with a recent Australian PBS claim study which expressed concern at the high rate of anxiolytic/hypnotic prescribing in those aged over 85 years of age.<sup>61</sup> A possible reason to account for the non-decline of anxiolytic/hypnotic use across age groups is that GPs may

encounter resistance when attempting to reduce use in older people who have been taking these agents for many years.<sup>376</sup>

When facility factors associated with psychotropic use in the sample of Tasmanian RACFs were examined, only anxiolytic/hypnotic use was significantly influenced by RACF size and location, with smaller facilities and northwest RACFs found to have a significantly higher rate of anxiolytic/hypnotic use. Several U.S. studies have reported a similar association with the use of antipsychotics and the size of the RACF.<sup>452,457</sup> Hughes *et al.* attributed the lower use to the possibility that larger facilities may be able to provide a wider array of services and activities, thus positively influencing resident behaviour and reducing the need for psychotropic medication.<sup>457</sup> Larger RACFs may also have more standardised policies and procedures to promote the quality use of psychotropic medication.

The RACFs situated in the northwest region of Tasmania were found to have a significantly higher rate of benzodiazepine prescribing than in the southern and northern regions. It should be noted that some of this prescribing could be attributed to the fact that the facilities in the northwest had a slightly higher proportion of female residents than the other regions, and the majority of facilities in this region had less than 31 beds; although these differences were not statistically significant between regions. Both female gender and small facility size were positively correlated with psychotropic use in this and other studies.<sup>452,457</sup> Some of the increased reliance on anxiolytic/hypnotic use in the northwest may also be due to other factors such as reduced access to psychogeriatric services or less RACF staff training on old age mental health conditions. Further research is needed to identify the specific reasons why benzodiazepines are prescribed more readily in this region.

One factor that does appear to positively influence psychotropic use in RACFs is nurse staffing levels which was not considered in the present study. Increased nurse staffing has been shown in many studies to be strongly associated with decreased psychotropic use.<sup>186,418,457,463</sup> It has been suggested that lower staffing levels result in less resident contact and poorer quality of care which is likely to directly impact the behaviour of residents, resulting in the need for more psychotropic agents to manage behaviour.<sup>463</sup> In the present study, an attempt was made to collect details on staffing levels among the participant RACFs, however, a complaint was made to the ethics committee by one of the facilities about the release of potentially sensitive commercial information, so this specific line of enquiry was not pursued any further.

### **11.3 Appropriateness of RACF psychotropic use**

High psychotropic use does not necessarily indicate misuse.<sup>91</sup> For this reason, the appropriateness of psychotropic use in this study was assessed by a combination of two criteria. To start with, the Beers criteria (2003) were applied to the present Tasmanian RACF prescribing

data (Table 26).<sup>85</sup> However, as the Beers criteria does not provide an indication of the appropriateness of antipsychotic prescribing, or offer comprehensive geriatric psychotropic dosing guidelines, the criteria for appropriate psychotropic medication use according to the 'Centers for Medicare and Medicaid Services, interpretive guidelines for long-term care facilities' based on OBRA-87 legislation, were also applied (Table 27).<sup>409</sup>

Although the Beers criteria have been criticised for not being 'international' in scope, are somewhat dated and categorise some medications (e.g. amitriptyline and diazepam) as potentially inappropriate even though they may be appropriate in certain clinical situations, they have widely been used over the past twenty years for identifying prescribing patterns in RACF studies.<sup>359</sup> In this 2006 Tasmanian study, a total of 7% and 6% of all residents in this study were taking the PIMs, diazepam and amitriptyline, respectively. These prevalence rates are three times higher than rates reported from a 2003 Finnish study of 1987 residents, where only 2% of the residents were taking diazepam and 2% were taking amitriptyline.<sup>421</sup> However, the incidence of PIM use was higher in a recent large cohort study from Scotland conducted in 2005-2006, where 11% of RACF residents were taking diazepam and 8%, were taking amitriptyline.<sup>435</sup>

The long-term care facility interpretive guidelines are a set of U.S. national consensus criteria that regulate psychotropic prescribing.<sup>409</sup> In this study it was not possible to complete several of the interpretive guidelines criteria as the specific indication for antipsychotic and anxiolytic use was not annotated on the resident case notes. Therefore, as an alternative measure, the number of residents prescribed antipsychotics and anxiolytic/hypnotics without a recorded mental health diagnosis was tallied to provide a minimum figure for this criterion.

According to the U.S. long-term care facility interpretive guideline criteria, over a third of the Tasmanian RACF residents' anxiolytic/hypnotic use, and a tenth of their antipsychotic use was potentially inappropriate because residents taking these agents did not have a recorded diagnosis of psychiatric illness. Many of these residents may have actually had an appropriate psychiatric indication but this may not have been formally diagnosed and/or documented in their medical records. However, the lack of documentation suggests that a low priority is given to the assessment and monitoring of mental illness in the Tasmanian RACF setting. Similar observations have been made in British, German and U.S. RACF studies.<sup>91,419,439</sup>

In regard to dosing, close to a third (29%) of anxiolytic/hypnotic users and 14% of antipsychotic users were taking doses exceeding the recommended maximum geriatric daily dose. Briesacher *et al's* U.S. study, investigating the appropriateness of antipsychotic prescribing, completed during 2000-2001, reported that that 19% of residents were taking excessive antipsychotic doses, which is 5% higher than the 14% figure found in this study.<sup>91</sup> In terms of the appropriateness of anxiolytic/hypnotic prescribing, Svarstad and Mount's study of

18 U.S. RACFs from 1986-1989, reported that 33% of residents received a benzodiazepine that exceeded recommended dosage, a figure close to the 29% of residents found in this study.<sup>462</sup>

The high number of excessive doses of both antipsychotic and benzodiazepine medications found in this study, and other RACF research, may be an indication that many of these medications are not effective, or lose effectiveness after a period of time, and that dosages are increased to optimise effect. However, even at high doses many of these psychotropic agents have limited effectiveness. Briesacher *et al.* noted in their study that nearly half of the residents taking antipsychotic treatment, many at excessively high doses, continued to display serious behavioural symptoms such as screaming or throwing food.<sup>91</sup>

#### **11.4 Multiple psychotropic agent use**

It was important to collect data on the number of RACF residents taking multiple psychotropic agents as the use of more than one psychotropic agent appears to be one of the strongest risk factors for falls and cognitive impairment.<sup>81,464</sup> In this Tasmanian study, almost a third of all residents were taking at least two or more psychotropic medications, with approximately one in ten residents taking three or more psychotropic medications. This multiple psychotropic agent prevalence is remarkably similar to prevalence data found in a U.S. RACF study in 2005, and slightly higher than multiple prevalence data from a Dutch RACF study in 2003 (comparative data is shown in Table 39).<sup>423,463</sup>

**Table 39: Multiple psychotropic use in studies conducted from 2003-2006**<sup>423,463</sup>

<b>Study</b>	<b>One + psychotropics (%)</b>	<b>Two + psychotropics (%)</b>	<b>Three + psychotropics (%)</b>	<b>Antipsychotic + benzodiazepine (%)</b>	<b>Two or more benzodiazepines (%)</b>
Tasmania, 2006	67	32	9	10	5
U.S., 2005	67	31	9	5	-
Netherlands, 2003	63	27	6	-	6

Of note are the high number of Tasmanian residents (10%) taking antipsychotic and benzodiazepine medication concomitantly. In effect, this means that nearly half the residents taking antipsychotic agents were also taking a benzodiazepine at the same time. One explanation for this high rate of multiple agent use is that the original psychotropic agent does not work effectively so another agent is added to the resident's medication regimen, without consideration of whether the original agent could be ceased or have its dosage gradually tapered down. GPs may also be reluctant to alter medication that another GP may have started.



However, without detailed medical recording, it is difficult to establish why this extent of multiple psychotropic prescribing is occurring in Tasmanian RACFs.

Another concern about multiple psychotropic use relates to the use of several benzodiazepine agents at the same time. With over 25% of benzodiazepines being prescribed at doses exceeding the maximum recommended geriatric dose, it was noted that 16% of all the benzodiazepine users were taking two different benzodiazepine agents concurrently. This multiple usage was not factored into the inappropriate dosing figures. Thus, the proportion of residents taking excessive doses of benzodiazepines in Tasmanian RACFs is probably higher.

### **11.5 Strengths and limitations**

The main strength of this study is its large sample size and the fact that the half the RACFs in the state were included. However, it is important to note that the RACFs included in this study were not randomly selected and may therefore not be representative of the RACF population in Tasmania. Another limitation is that information on diagnoses and indications for psychotropic drug use was not detailed enough in the medical records so that several of the appropriateness criteria could not be examined in the depth required. Finally, the validity of our findings is limited by the accuracy of the pharmacist prepared case-notes, derived from the facility medical notes, both of which may have been poorly documented or incomplete.

In this study, the RACF psychotropic prevalence and inappropriateness of prescribing was compared between Tasmania and different Australian states and countries. It should be acknowledged that the resident case-mix in different areas of Australia and other countries may vary. For instance, some areas may provide a greater level of support to older people with mental health conditions in the community and allow them to remain at home. Such provision of community care in a particular region may result in fewer numbers of RACF; however, the case-mix of RACF residents may have more severe levels of behavioural and psychological symptoms with a consequent higher requirement for psychotropic use. Unfortunately, it is difficult to determine the exact incidence of dementia and other mental health conditions in RACFs in a given area, or even in a given RACF, due to inadequate assessment and poor medical note recording in this setting. In future studies validated diagnostic tools such as the ADAS-Cog, Hamilton Agitation Index and Geriatric Depression Scale should ideally be used to ascertain exact levels of psychogeriatric conditions so that relationships between case-mix and psychotropic prescribing can be explored in greater depth.

### **11.6 Conclusion**

In conclusion, when the psychotropic prevalence rates from this study are compared to other Australasian RACF prevalence rates, the current level of benzodiazepine prescribing is of major

concern; at three times that reported in Sydney and New Zealand. Further, there was a high level of potentially inappropriate psychotropic prescribing as indicated by validated international inappropriateness prescribing scales, in terms of both inappropriate agents and high doses utilised. Finally, a large proportion of residents, at least a third, were taking several psychotropic agents at the same time, increasing their risk of falls and cognitive impairment.

When known associations were sought to account for this high level of psychotropic use it was found that few of the selected facility characteristics explained much of the variance in rates of prescribing. Some of the resident characteristics, specifically age and gender, were shown to influence usage patterns, but not among all psychotropic agents the same way. For this reason, in-depth qualitative analysis is required to understand why antipsychotics and benzodiazepine agents are used so extensively in RACFs and determine who or the factors influencing their use. Another important consideration which has not been examined thus far is the extent of dose variation of psychotropic medication, another important indicator of the quality use of psychotropic medication.

## CHAPTER TWELVE: INTRODUCTION AND METHOD

### ASSESSING PSYCHOTROPIC VARIATION IN TASMANIAN RACFS

#### **12.1 Reviewing and reducing antipsychotic and benzodiazepine medication**

Another important aspect of psychotropic use in the RACF setting is the length of time residents take them. In view of the modest benefits and significant risks associated with antipsychotic and benzodiazepine use in frail older people, most professional and health-policy based guidelines recommend these medications be initiated judiciously, at low dosage, monitored for effect, and for dosage reduction attempts to be made at regular intervals with the view to eventual cessation.<sup>58,95,96,164,261</sup> One of the barriers to regular dose reduction attempts appears to be concerns of health professionals that the behavioural and psychological symptom/s of the resident may return if medication doses are reduced.<sup>244,426,465</sup> However, much of the research evidence relating to the withdrawal of psychotropic medication does not support this concern.<sup>270,466</sup> The majority of studies involving the withdrawal of psychotropic medication in RACFs have shown that they can be withdrawn without causing harm, and in about half the studies, discontinuation actually benefits some residents.<sup>467</sup> It should be qualified that in a recent literature review evaluating medication withdrawal trials in older people, the authors state that definite conclusions about the success of psychotropic medication withdrawals were limited by the fact that most of the trials were very small.<sup>467</sup>

##### **12.1.1 Antipsychotic withdrawal**

Of eight studies performed in RACF residents, primarily those with BPSD, no significant differences in various behavioural, psychiatric, cognitive and functional measures were observed after antipsychotic medications were withdrawn (see Table 40). This absence of behavioural exacerbation was first noted in several RACF intervention trials, which showed that when antipsychotics were ceased, the level of BPSD remained static or even improved.<sup>468</sup>

In a pilot 4-week antipsychotic withdrawal RCT conducted by Bridges-Parlet *et al.* of 36 RACF residents, when antipsychotics were ceased, the frequency of aggression did not differ between intervention and placebo groups, and only 10% of placebo residents experienced worsened BPSD.<sup>469</sup> In a more comprehensive, 6-week, placebo-controlled, crossover study of 58 residents, again, no significant difference was observed in behavioural scores between residents who had either haloperidol, thioridazine or lorazepam withdrawn or remained on these treatments.<sup>470</sup> It should be noted, however, that this latter study also included intensive psychosocial strategies which may have influenced the study outcome.<sup>470</sup>

**Table 40: Summary of RACF antipsychotic withdrawal studies**

Reference	Setting	Trial design	Design and components of the intervention	Outcomes
<b>Thapa et al 1994</b> <sup>468</sup>	12 RACFs, U.S.	Longitudinal prospective	Compared residents on treatment (n=207) with residents who discontinued treatment (n=64) after 26 weeks	Frequency of BPSD similar between groups. Improvement in affect. No deterioration in function
<b>Bridges-Parlet et al. 1997</b> <sup>469</sup>	1 RACF, U.S.	Randomised Controlled Trial (RCT)	22/36 residents withdrawn in 4 week trial	No significant difference between withdrawn and treated residents in behaviour. Most withdrawn residents remained off psychotropic medication after trial
<b>Cohen-Mansfield et al, 1999</b> <sup>470</sup>	1 RACF, U.S.	Double-blind cross-over	58 residents- given psychotropic medication or placebo for 6 weeks, then crossed over	No impact of withdrawal on behaviour with CMAI or other rating score
<b>Van Reekum et al, 2004</b> <sup>471</sup>	1 RACF, Canada	RCT	34 residents on antipsychotics randomised to placebo or normal treatment for 6 months	Residents remaining on antipsychotics had more physical aggression. Placebo group developed more apathy - but improved cognitive functioning
<b>Ballard et al 2004</b> <sup>466</sup>	2 centres in RACFs, U.K.	RCT	100 residents randomised to treatment or withdrawal for 3 months	Residents with lower NPI scores (less severe behaviour) displayed less agitation off antipsychotics. Residents with more severe BPSD worsened symptoms after withdrawal
<b>Ruths et al, 2008</b> <sup>472</sup>	13 RACFs, Norway	RCT	55 residents randomised to treatment or withdrawal for 4 weeks	NPI either stayed stable or improved in withdrawn residents. 23/27 residents stayed off antipsychotics after trial
<b>Ballard et al, 2008</b> <sup>270</sup>	Multi-centre, RACFs in U.K.	RCT	163 residents randomised to treatment or withdrawal	No significant difference between treatment and withdrawal in behaviour scores. Residents with more severe BPSD benefited more from treatment than placebo.
<b>Kleijer et al 2009</b> <sup>473</sup>	Multi-centre RACFs in Netherlands	Longitudinal retrospective	520 residents tracked when antipsychotic treatment withdrawn	Two thirds of residents (68%) remained stable or improved with respect to behaviour at 3 months, this figure was 58% at 6 months post withdrawal.

**Table 41: Summary of RACF benzodiazepine withdrawal studies**

Reference	Setting	Trial design	Design and components of the intervention	Outcomes
<b>Salzman et al 1992</b> <sup>474</sup>	1 RACF, U.S.	Prospective Observational	25 residents had benzodiazepines tapered off	Significant improvement in memory and cognitive functioning. No increase in anxiety, agitation or sleeplessness.
<b>Gilbert et al. 1993</b> <sup>475</sup>	2 RACFs, Australia	Controlled Trial	1 RACF intervention, 1 control RACF. Intervention residents offered withdrawal	Proportion of residents taking benzodiazepines decreased from 70% to 35%. Improvement in emotional responsiveness. No adverse consequences associated with withdrawal
<b>Harbraken et al, 2004</b> <sup>476</sup>	10 RACFs. Belgium	RCT	55 residents randomised to placebo or treatment for 12 months	Daily functioning significantly improved in placebo residents. Subjective decline in sleep quality in placebo group

Several antipsychotic withdrawal studies have shown that those residents with the most severe behavioural symptoms or those taking higher baseline doses, a factor which may indicate greater BPSD severity, were more likely to develop exacerbations of behaviour when their medication was withdrawn.<sup>466,471,472</sup> In Ballard *et al.*'s discontinuation study of 100 RACF residents over a 3 month period, residents with baseline NPI scores < 14 experienced significantly greater reductions in agitation scores than the continuing-treatment group ( $P < 0.02$ ). In contrast, those residents with NPI scores > 14 were significantly more likely to develop marked behavioural problems if antipsychotic therapy was ceased ( $P < 0.01$ ). Another relevant finding of this study is that there was no significant difference in quality of life parameters between groups, suggesting that antipsychotic treatment had limited impact on these types of measures.<sup>466</sup>

Recent studies assessing the impact of antipsychotic withdrawal have also provided evidence that antipsychotic treatment can be withdrawn without detriment to the resident in most cases.<sup>270,473</sup> When Ballard *et al.* conducted the large DART-AD RCT, a 12-month antipsychotic withdrawal study in 165 RACF residents, there was no difference between the treatment and placebo groups in neuropsychiatric symptoms, although it was noted that residents with more severe symptoms appeared to benefit from continued treatment. This trial also reported that residents continuing to take antipsychotics experienced a significant deterioration in verbal fluency and non-significant trends for worsening of functional ability and parkinsonism.<sup>270</sup> In another Dutch observational longitudinal study, the course of BPSD after antipsychotic withdrawal was evaluated in 520 residents. Of these residents, over two thirds (68%) remained stable or improved at 3 months compared with their behavioural scores before withdrawal. This figure decreased to 58%, 6 months after withdrawal.<sup>473</sup>

Withdrawing antipsychotic medication was reported to be successful in the majority of residents of RACFs. Half of the reviewed studies found no deterioration of behaviour, functional ability or quality of life in at least two thirds of residents.<sup>270,466,472,473</sup> It should be noted that continued duration of antipsychotic treatment may benefit those residents with more severe BPSD, but this possibility needs to be weighed up against the adverse effects associated with treatment. The weight of evidence strongly supports the need to consider regular trials of antipsychotic withdrawal in older people with dementia.

### **12.1.2 Benzodiazepine withdrawal**

Several studies have shown that older patients reliant on low doses of benzodiazepines may be tapered in a short period of time with psychological support.<sup>156,477</sup> With carefully managed withdrawal in motivated patients the success rate for stopping benzodiazepines is as high as

80%.<sup>155,478</sup> However, as anxiety and insomnia are chronic relapsing conditions, the rate of relapse after withdrawal is variable, with relapse rates recorded between 43% and 92%.<sup>155,479</sup>

There have been three published studies to assess the effect of withdrawing benzodiazepines in RACFs, all of which were performed over 15 years ago (See Table 41).<sup>474-476</sup> Salzman *et al.* reported that measures of cognition and memory improved in those residents ceasing benzodiazepine treatment, in comparison to residents who continued to take these medications.<sup>474</sup> When Gilbert *et al.* performed an intervention study in two RACFs in Adelaide, one which was an intervention RACF and the other the control, the proportion of residents taking benzodiazepines in the intervention RACF decreased from 70% to 35% over the 3-month trial period. In those residents who had ceased treatment, there were no differences found in mean MMSE scores, subjective health scores or sleep satisfaction scores; however significant differences were found in both positive and negative affect in emotional responsiveness scores.<sup>475</sup> Harbraken *et al.* performed a benzodiazepine withdrawal study in 10 Belgian RACFs but were hampered by a poor recruitment rate, influenced by selection of residents by their GP and the RACF nursing staff.<sup>476</sup> Out of a potential 328 residents taking benzodiazepines, only 33 residents participated in the trial. The authors concluded that though the study sample was too small to draw definitive conclusions about the long-term effect of gradual withdrawal of benzodiazepines, a significant positive difference emerged in the level of functioning in those residents who were withdrawn.<sup>476</sup>

Another, more recent study, provides additional evidence for the benefit of reducing and withdrawing benzodiazepines in older people.<sup>480</sup> Curran *et al.* recruited 104 older long-term users of hypnotic benzodiazepine users in the U.K. and allocated them to one of two groups: Group A's benzodiazepine dose was tapered from week 1 of the trial; Group B were given their usual dose for 12 weeks after which the dose was tapered. An additional Group C of 35 patients who did not wish to withdraw from benzodiazepines participated as controls. All participants were assessed at baseline, 12 and 24 weeks and 50% were reassessed at 52 weeks. All patients undergoing withdrawal visited a psychologist at initial recruitment and at all assessment times. In addition, a pamphlet on sleep hygiene was provided to each patient and telephone support offered between psychologist visits.<sup>480</sup>

Of all patients in Groups A and B, 80% had successfully withdrawn benzodiazepines by 24 weeks. There was no significant differences between Groups A or B throughout the trial; however by 24 weeks, Groups A and B showed significantly higher scores on 'physical health' and 'social functioning' measures. In addition, residents in the withdrawal groups attained significantly higher scores in several cognitive and psychomotor tests, including working memory, reaction times, alertness and improved accuracy at information processing at 24 and

52 weeks. Notably, there were no significant differences between the control Group G and the withdrawal groups at week 24 and 52 weeks in sleep quality or withdrawal symptom scores.<sup>480</sup> These few trials provide evidence of the potential benefits to be gained by reducing benzodiazepine use in older residents of RACFs. The authors in two of the trials emphasised that successful interventions required gradual tapering regimes, information about sleep and sleep hygiene and the provision of psychosocial strategies to manage sleep and anxiety symptoms.<sup>476,480</sup>

The recommended rate of tapering and method of benzodiazepine medication for older people has aroused considerable debate.<sup>481</sup> The optimal duration of withdrawal is not clear and probably varies from patient to patient. The most common recommendation is to withdraw benzodiazepine medication in steps of about one tenth of the daily dose every 1-2 weeks, with various researchers suggesting optimal withdrawal times of 6-8 weeks.<sup>154,482</sup> Some authors advocate switching the patient over to diazepam as this agent's slow elimination ensures a gradual fall in plasma levels, while its availability in low-dosage forms permits small dosage reductions.<sup>154</sup> However, when a 2006 Cochrane review examined 8 studies of pharmacological interventions for benzodiazepine withdrawal there was no difference between withdrawal symptoms in people taking long or short-acting agents.<sup>483</sup> Thus, switching to diazepam before tapering was not supported by this review.<sup>481</sup> Some health practitioners also advocate the use of adjunctive medications to reduce withdrawal severity, however, the Cochrane review did not find any pharmacological agents to be helpful, aside from carbamazepine (200-800mg/day) which reduced some withdrawal symptoms in patients receiving diazepam equivalent doses above 20mg per day.<sup>484</sup>

It should be noted that symptoms of withdrawal in older people may be different to those experienced by younger people.<sup>133</sup> In a prospective study of benzodiazepine withdrawal in older inpatients, rebound anxiety and insomnia symptoms were not commonly experienced. The authors speculated that the slower clearance of benzodiazepine medication in older people may modulate the symptoms of withdrawal.<sup>156</sup>

## **12.2 Psychotropic review practice in Residential Aged Care Facilities**

The only way to determine if a psychotropic medication is still required, and whether the dose remains appropriate, is to attempt to reduce the dose while closely monitoring the resident for improvement, stabilisation or decline.<sup>485</sup> In 2006, new RACF Federal regulations were introduced in the U.S. which specify that 'gradual dose reductions' must be attempted with any psychopharmacological medication twice a year. Furthermore, gradual dose reduction attempts are now mandated quarterly for all hypnotic medication.<sup>409</sup> According to the U.S. Long-term care facility interpretive guidelines, 'Gradual Dose Reduction' is defined as:



*'The stepwise tapering of a dose to determine if symptoms, conditions or risks can be managed by a lower dose or if the medication can be discontinued.'*<sup>409</sup>

These guidelines recognise that the time frames and duration of dose reduction attempts depend on such factors as clinical history of the resident and pharmacokinetic characteristics of the medication. They also acknowledge that medications such as benzodiazepines require more gradual tapering to minimise or prevent withdrawal symptoms or rebound phenomenon.<sup>409</sup>

In some cases, principally with benzodiazepines, it is acknowledged that some older residents who have been maintained on medication for many years may experience a significant worsening of symptoms when attempts are made to withdraw it, even when the dose is tapered very gradually.<sup>301</sup> In such cases, it is usually less disruptive to residents to leave them on the medication and monitor them on a regular basis. If adverse effects do become problematic as the person grows older, dose reduction, rather than complete discontinuation, may be the best compromise.<sup>301</sup>

Current guidelines in Australia advise that antipsychotic therapy used for BPSD be reviewed every 3-6 months.<sup>58,164</sup> Benzodiazepines are not indicated for sleep disturbance and anxiety for periods longer than 2-4 weeks, with long-term users advised to reduce use whenever practicable.<sup>95</sup> It is not known if these guidelines are followed in actual practice in Tasmanian RACFs.

### **12.2.1 Research on psychotropic review practice**

Although there are many RACF psychotropic prevalence studies in the research literature, both national and international, there are very few research studies that have investigated psychotropic review practices in the RACF setting. The only known published Australian psychotropic review study was performed over 15 years ago by Snowden and Vaughan in 38 Central Sydney RACFs, 9 months after Snowden *et al's* initial 1993 prevalence study.<sup>38,426</sup> They reported that over two thirds (65%) of residents on psychotropic medications were taking exactly the same agents, at exactly the same dose, nine months later. Only a third of antipsychotic doses and a quarter of benzodiazepine doses in the Central Sydney RACFs were reduced or ceased throughout that period.<sup>426</sup>

There were even fewer attempts made to reduce psychotropics in a Canadian research study conducted in 24 RACFs, where only 7% of antipsychotic medications, and 2% of benzodiazepine medications, were ceased or showed an attempt made for dose reductions in a year of data collection, from 2002 and 2003.<sup>424</sup> Likewise, in a longitudinal Norwegian study, 75% of the residents of RACFs taking antipsychotic medication, and 66-72% of residents taking anxiolytic/hypnotic medication in 2004 were still taking these same medications a year later.<sup>59</sup>

These few international studies suggest that review of antipsychotic and benzodiazepine medication in RACFs is problematic around the world.

In response to Professor Snowden's research and to concerns expressed from the public and professional bodies, a Senate committee was formed to investigate claims of high psychotropic use.<sup>38,486</sup> In their 1995 report, entitled; 'Psychotherapeutic medication in Australia', the Senate Committee concluded that:

*'the lack of monitoring, or review of psychotropic agents, led to high levels of antipsychotics and benzodiazepines being prescribed for excessive periods, for little apparent benefit'.<sup>486</sup>*

The Senate Committee attributed much of the over-prescribing of psychotropic medication to poor RACF review practices. But is this really the case? It is difficult to establish if the lack of psychotropic review has led to extensive psychotropic use in the RACF setting because there are few studies that have tracked utilisation of psychotropic medication by the same residents over consecutive years in Australian RACFs.

### **12.3 Aim**

The aim of this research study, the second study in the first stage of the thesis, was to determine the alteration in antipsychotic and benzodiazepine doses of residents from 2006 to 2007 as an indication of the frequency of review and dose reduction attempts, currently recommended by Australian and international guidelines.

### **12.4 Study design**

This follow-up study was a second retrospective cross-sectional study of prescribing data.

### **12.5 Data Collection**

Medication review services were conducted for 33 of the original 40 RACFs in 2007. Data on psychotropic medication use was collected from pharmacist case-notes prepared from medical notes and medication charts when medication reviews were performed at these RACFs. All residents of a RACF who had a medication review in both 2006 and 2007 were included in the study.

#### **12.5.1 Data entry and analysis**

Only residents who had a medication review in 2006 as well as in 2007 were entered into a separate Microsoft® Office Access database and de-identified. Resident data were excluded if

the medication data was incomplete. As before, medications were considered as 'regular' if they were taken on four or more days per week in the last month.

In order to map drug and dosage variation in detail, the variation in both antipsychotic and benzodiazepine dosages between years were categorised as 'dose decreased', 'dose increased' and 'same dose'. Medications stopped between the 2006 and 2007 medication reviews were categorised as 'ceased'. Medications initiated between the 2006 and 2007 medication reviews were categorised as 'started'.

In addition, all daily dosages of benzodiazepines and antipsychotics were converted into Diazepam (DZP) and Chlorpromazine (CPZ) equivalents, respectively.<sup>482,487</sup> Mean DZP and CPZ equivalents were used to assess the overall dosage alteration for benzodiazepines and antipsychotics between 2006 and 2007. Three different references were used to calculate the equivalents of antipsychotic and anxiolytic/hypnotic medications.<sup>482,487</sup>

The following DZP equivalences were adopted for this study: 10 mg of diazepam was considered to be equivalent to: 0.5 mg alprazolam, 1 mg flunitrazepam, 1 mg lorazepam, 10 mg nitrazepam, 20 mg oxazepam, 20 mg temazepam, 15 mg zopiclone and 20 mg zolpidem.<sup>432</sup> The following CPZ equivalencies were used in this study: 100 mg of chlorpromazine was considered to be equivalent to 2 mg risperidone, 5 mg olanzapine, 75 mg quetiapine, 7.5 mg aripiprazole,<sup>433</sup> 2 mg haloperidol, 100 mg thioridazine, 24 mg pericyazine and 5 mg trifluorperazine.<sup>488</sup>

## **12.6 Statistical analysis**

All statistical analyses were performed using StatView®, version 5.0.1 (SAS Institute Inc, Cary NC, USA). Categorical variables between groups were analysed using chi-square analysis ( $\chi^2$ ). The Fishers Exact Test was used when at least one of the variables had less than five residents or values. The Mann-Whitney test was applied to compare non-parametrically distributed variables across groups. Paired t-tests were used to analyse the differences in continuous level data, specifically, the difference between benzodiazepine and antipsychotic dosage for residents who used these drugs in 2006 as well in 2007. 'P' values of 0.05 or less were considered statistically significant.

## **12.7 Ethical approval**

Approval for this second RACF data collection was granted by the Tasmania Social Sciences Human Research Ethics Committee.

## CHAPTER THIRTEEN: RESULTS

### ASSESSING PSYCHOTROPIC REVIEW IN TASMANIAN RACFS

#### **13.1 Baseline data collection**

RMMR services were provided for residents in 33 of the original sample of 40 RACFs throughout 2007. Medication review services were not conducted in the remaining seven RACFs because three RACFs had closed and the other four pharmacies changed their medication review providers. The system of RMMR provision used at this time was that each RACF was visited for RMMR provision on an annual basis. The three accredited pharmacists spend 1-4 days conducting RMMRs on all residents at each RACF at a time. The majority of RACFs had their RMMRs conducted exactly 12 months after the 2006 RMMR (n=26). However, the period between RMMRs ranged from 11 months (2 RACF) to 13 months (3 RACFs) and 14 months (2 RACFs).

##### **13.1.1 Resident characteristics**

Of 1 957 residents who had their medications reviewed annually in the sample of 33 RACFs in 2006, 1 307 residents (67%) of these residents also had an annual medication review service in 2007. A total of 650 resident case-notes were not reviewed in this period because residents had died, left the facility or were hospitalised. The demographics of this sample of RACF residents differed slightly from the original sample in that there were more females and they were slightly older. Of the 1 307 residents having two consecutive medication reviews, 76.9% were female and 23.1% were male. The mean age of residents was 84.9 years (S.D. 8.8); the mean age of the women was 86.0 years (S.D. 7.8) and the men, 81.2 years (S.D. 10.5).

##### **13.1.2 RACF characteristics**

The size of the 33 RACFs varied between 16 and 152 beds, with a mean facility size of 60 beds. The 33 RACFs were divided into three regions; south, north, northwest as follows: 16 (632 residents) were located in the south, 14 (546 residents) were located in the north of Tasmania, and 3 (129 residents) were located in the north-west.

#### **13.2 Psychotropic prevalence amongst residents**

Of the 1 307 residents, 827 (63.3%) were taking one or more psychotropic medications on a regular basis in 2006. This number increased to 855 residents, almost two thirds (65.4%) of the whole population, in 2007. In 2007, 30.3% of the residents were taking two or more

psychotropic drugs per day and 7.3% were taking three or more psychotropic drugs per day. Table 42 provides a breakdown of baseline psychotropic use.

**Table 42: Number (%) of RACF residents taking psychotropic medication regularly in 2006 and 2007**

<i>Psychotropic</i>	2006	2007
<b>Any psychotropic</b>	827 (63%)	855 (65%)
<b>Antipsychotics</b>	263 (20%)	280 (21%)
<b>Anxiolytic/hypnotics</b>	487 (37%)	500 (38%)
<b>Antidepressants</b>	457 (35%)	471 (36%)

Overall, both antipsychotic and anxiolytic/hypnotic use increased slightly in this resident cohort between 2006 and 2007; antipsychotic prevalence: 20.1% vs. 21.4% ( $\chi^2 = 0.6$ ,  $df = 1$ ;  $P = 0.4$ ) and anxiolytic/hypnotic prevalence: 37.3% vs. 38.3% ( $\chi^2 = 0.2$ ,  $df = 1$ ;  $P = 0.6$ ).

### **13.3 Extent of dosage variation of antipsychotic and benzodiazepine medication among residents**

Like the prevalence data, the mean CPZ equivalence in the sample of 33 RACFs increased slightly from 107.1mg per day in 2006 to 109.3mg per day in 2007. The mean DZP equivalent remained unaltered at 10.4 mg per day in both 2006 and 2007.

The following analyses include all residents who used a benzodiazepine or antipsychotic drug in 2006 or in 2007, and the residents who started or ceased an antipsychotic or benzodiazepine medication in this time frame.

#### **13.3.1 Regional alteration in mean CPZ equivalents between 2006 and 2007**

Table 43 represents the increase in mean chlorpromazine equivalent in those residents taking antipsychotic medication in the north, north-west and south regions between 2006 and 2007.

**Table 43: Increase in mean antipsychotic dosage (CPZ) between 2006 and 2007 in regional areas of Tasmania**

<b>Region</b>	<b>Difference in mean CPZ equivalent (mg)</b>	<b>N</b>	<b>P value</b>
North	11.82	115	0.21
North-west	14.36	38	0.17
South	4.05	157	0.41
<b>Total</b>	<b>8.20</b>	<b>310</b>	<b>0.07</b>

The overall mean dosage of antipsychotic medication taken by residents increased by 8.20 mg of chlorpromazine equivalents between 2006 and 2007; however, this difference was not statistically significant. The increase in antipsychotic dosage was the highest for the north-west region with a 14.36 mg CPZ equivalent increase and lowest for the south region (4.05 mg CPZ equivalent increase). None of these mean chlorpromazine equivalent differences were statistically significant.

### 13.3.2 Regional alteration in mean DZP equivalents between 2006 and 2007

Table 44 represents the difference in mean diazepam equivalent between 2006 and 2007 for the three regions.

**Table 44: Alternation in mean benzodiazepine dosage (DZP) between 2006 and 2007 in regional areas of Tasmania**

Region	Difference in mean Diazepam equivalent (mg)	N	P value
North	-0.29	237	0.61
North-west	1.73	55	<b>0.047</b>
South	0.48	269	0.26
<b>Total</b>	0.28	561	0.39

The mean dosage of benzodiazepines increased overall by 0.28 mg diazepam equivalents between 2006 and 2007; however, this difference was not statistically significant. Each region showed a different level of dose variation, ranging from a 0.29 mg diazepam equivalent decrease in benzodiazepine dosage in the north, to a 1.73 mg diazepam equivalent increase in benzodiazepine dosage in the north-west. Only the difference in mean diazepam equivalents in the north-west region was statistically significant ( $t = 2.0$ ,  $P < 0.05$ ).

### 13.3.3 Initiation of new psychotropic medication

The proportion of residents started on antipsychotic or benzodiazepine treatment after the 2006 medication review also varied by region. (Table 45)

**Table 45: Difference in psychotropic initiation between 2006 and 2007**

Region	Residents started on antipsychotic treatment	Residents started on benzodiazepine treatment
	N (%)	N (%)
North	20 (4)	32 (6)
Northwest	9 (7)	11 (9)
South	20 (3)	32 (5)
<b>Total</b>	49 (4)	75 (6)

Of the 1307 residents, 4% were initiated on antipsychotics and 6% were started on benzodiazepines between the 2006 and 2007 medication review. The rate of psychotropic initiation was higher in the northwest; however, this difference was not statistically significant: Antipsychotics: ( $\chi^2 = 4.3$ ,  $df = 2$ ;  $P = 0.1$ ), benzodiazepines: ( $\chi^2 = 2.4$ ,  $df = 2$ ;  $P = 0.3$ ).

### 13.3.4 Alteration in psychotropic medication dose from 2006 to 2007

Table 46 displays a summary of all alterations made to antipsychotic or benzodiazepine medications between 2006 and 2007.

**Table 46: Alteration in antipsychotic and benzodiazepine use between 2006 and 2007**

	Antipsychotic use N (%)	Benzodiazepine use N (%)
Drug ceased	31 (11.9)	62 (12.7)
Dose increased	38 (14.6)	69 (14.2)
Dose decreased	39 (14.9)	52 (10.7)
Same dose	153 (58.6)	304 (62.4)
<b>Total</b>	<b>261† (100)</b>	<b>487 (100)</b>

†NB. Dose information for two listed antipsychotics in consecutive years was unavailable

Specifically, 58.6% of residents were taking the same dose of antipsychotic and 62.4% the same dose of benzodiazepine in both years. Over 14% of residents had their dosage of antipsychotic or benzodiazepine agent increased; 26.8% of residents taking antipsychotics had their dose reduced or ceased and less than a quarter of residents taking benzodiazepines (23.4%) had their dose reduced or ceased from the 2006 to the 2007 medication review.

Table 47 displays the alteration in psychotropic use in the three different regions. The RACFs in the Northwest region were more likely to increase doses of antipsychotics and benzodiazepines and less likely to reduce doses or cease medications; however, none of these differences in dosage alteration practices were statistically significant.

**Table 47: Alteration in antipsychotic and benzodiazepine use between 2006 and 2007**

Antipsychotic use	North	North-west	South	Total N (%)
Ceased	16 (17)	3 (10)	12 (9)	31 (12)
Dose increased	12 (13)	7 (24)	19 (15)	38 (15)
Dose decreased	13 (14)	3 (10)	23 (18)	39 (15)
Same dose	54 (57)	16 (55)	83 (65)	153 (59)
<b>Total</b>	<b>95 (100)</b>	<b>29 (100)</b>	<b>127 (100)</b>	<b>261 (100)</b>
<b>Benzodiazepine use</b>	<b>North</b>	<b>North-west</b>	<b>South</b>	<b>Total N (%)</b>
Ceased	31 (13)	3 (5)	28 (10)	62 (11.1)
Dose increased	24 (10)	7 (13)	38 (14)	69 (12.3)
Dose decreased	21 (9)	4 (7)	27 (10)	52 (9.3)
Same dose	129 (54)	30 (55)	144 (53)	303 (54.0)
<b>Total</b>	<b>237 (100)</b>	<b>55 (100)</b>	<b>269 (100)</b>	<b>561 (100)</b>

## CHAPTER FOURTEEN: DISCUSSION

### ASSESSING PSYCHOTROPIC REVIEW IN TASMANIAN RACFS

#### 14.1 Review of psychotropic medication

Current Australian and international guidelines recommend that older people taking antipsychotics for BPSD are reviewed every 3-6 months with the aim of reducing and eventually ceasing this medication.<sup>164</sup> Similarly, long-term users of benzodiazepines should be encouraged to reduce usage at regular intervals.<sup>95</sup>

When the dosages of antipsychotics and benzodiazepines in the same group of Tasmanian RACF residents in 2006 and 2007 were compared, more than half of residents taking antipsychotics and nearly two thirds of residents taking benzodiazepines were taking exactly the same agent, at the same dose. Less than a quarter of the residents had their psychotropic doses reduced, or medication ceased, as recommended by professional guidelines.<sup>164</sup> In addition, mean equivalence measures for antipsychotics and benzodiazepines did not change appreciably in the same cohort of residents from year to year providing evidence of minimal dosage variation.

These results strongly suggest that Australian guidance recommending regular review of antipsychotic and benzodiazepine medications was not followed, nor were regular attempts at dose reduction made for the majority of residents in our Tasmanian RACFs. As the Australian Senate committee reported more than ten years before this data collection, many residents are remaining on these medications for extended periods. This finding is of particular concern for long-term (>12 months) antipsychotic users with dementia where extended use of these medications has recently been linked to a significantly increased risk of mortality and cerebrovascular event.<sup>266</sup>

The reasons for this lack of psychotropic medication review are unclear. It may be related to problems with medical service provision to RACFs to review medications. The availability of GPs to attend RACFs in Australia is an issue of growing concern.<sup>36</sup> Despite escalating numbers of residents with increasingly complex medical needs, the number of GP attendances to RACFs has been decreasing over recent times due to factors such as workforce shortages, high GP workloads, and part-time work preferences.<sup>164</sup> A national 2004 survey found that over half (56%) of RACFs sometimes had difficulty obtaining GP input for routine services such as writing and reviewing medication charts and prescriptions.<sup>489</sup>

One of the main justifications that is given for the introduction of funded pharmacist-led medication reviews in Australia is to promote the appropriate use of psychotropic medication in RACFs via '*regular medication reviews and nurse education by consultant pharmacists*'.<sup>39,46</sup> All the residents audited for this research had had at least two RMMRs, yet the majority of



psychotropic agents and dosages of these agents had not been altered in spite of the pharmacist review process. The findings of this research suggest that the present RMMR and associated QUM program exert a limited effect on the extent of psychotropic review. The reasons for this are unknown but may be related to GPs not taking up recommendations from pharmacists, or resistance from other health professionals to altering these medications. Another reason for the limited review of antipsychotic and benzodiazepine medication may be associated with a general lack of awareness of psychotropic guidelines relating to review and dose tapering. More detailed research is required to establish the determinants of psychotropic prescribing in the residential aged care setting and to ascertain the barriers to the review of these agents.

There may, naturally, also be concern that reducing doses of antipsychotic and benzodiazepine medications may exacerbate the resident's behaviour, sleep problem or anxiety symptoms. Paradoxically, as outlined earlier, research shows that reduction of antipsychotic and benzodiazepine treatment has made little difference to behavioural levels and can even be beneficial in the trials where sedative use has been withdrawn.

The rates of psychotropic initiation in the sample residents over the 12 month period were also examined in this study. The rate of initiation of benzodiazepine and antipsychotic medication in this Tasmanian study was minimal at 6% and 4% of residents, respectively.<sup>426</sup> In other words, only one in twenty-five residents, on average, were started on an antipsychotic medication throughout the year-long period between audits, with slightly more residents started on benzodiazepines. Nine months after his original study, Snowdon *et al.* performed a repeat audit in the same RACFs in Central Sydney. Similarly to the present study, only 5% of residents were actually started on new psychotropic therapy, as opposed to 65% of residents remaining on the same medication at the same dose.<sup>426</sup> Thus, it appears as if the prescribing of new psychotropic agents in Tasmanian RACF amongst long-term residents, like in Sydney, is relatively modest. As the Senate Committee asserted in 1995, the lack of review of agents may account for much of the high prevalence of psychotropic use.<sup>486</sup>

In the first study in the first stage of this thesis, the northwest region was found to have significantly higher rates of RACF benzodiazepine use. In this second study, differences were also observed in the review pattern of benzodiazepine agents in the northwest and the southern and northern regions. Although the only statistically significant difference found between regions was in the increase in mean diazepam equivalence in RACFs from 2006 to 2007, the northwest region also had the highest proportion of residents started on new benzodiazepine medication and the fewest dose reductions/cessations in this period. It is apparent that benzodiazepines are not only used more extensively in the northwest region but that RACF residents from this region are more likely to have doses increased, fewer doses decreased or ceased, and more benzodiazepines initiated than their southern and northern counterparts.

The finding that rates of psychotropic use are higher in the northwest, along with the observation of inferior review practice, adds more weight to the theory that there is a strong link between high prevalence rates and inadequate review practice.<sup>486</sup> The reasons for this difference in benzodiazepine review between the regions in Tasmania are unclear. Further research into psychotropic prescribing practices in the northwest is required as a matter of priority.

## **14.2 Strengths and limitations**

The major strengths of this present study were its considerable sample size and the ability to track a sizable proportion of residents over consecutive years to assess dose alteration. This study does have several limitations though. Firstly, two data measures were examined at a single point of time. It is possible that alterations were made to the psychotropic medication doses between collection points and then readjusted back to original dose, meaning that the number of dose alterations could be higher than recorded.

With regards to initiation of new psychotropic agents in the RACFs, this study only tracked a sample of the same long-term residents over a 12 month period. This study did not consider the initiation of psychotropic agents in new residents which has been shown to be high. For example, a large Canadian retrospective cohort study of over 19 700 RACF residents found that 24% of new residents were started on antipsychotics within 12 months of admission.<sup>490</sup> Therefore, the actual rate of psychotropic initiation in the Tasmanian RACFs could be higher than that demonstrated in this study.

Finally, it should be noted that conclusions of this study of Tasmanian RACF psychotropic review may not be generalisable to other groups of RACFs elsewhere in Australia. It is of considerable interest, however, that the rates of unchanged psychotropic medication from year to year in this study, the 2003 Central Sydney review study and the Norwegian study are very similar, ranging from 60% to 75% of residents.<sup>59,426</sup> The similarity in the extent of unchanged medications between these three studies provides evidence of a widespread lack of review of psychotropic medication in RACFs. Residents of these facilities are remaining on these medications for unnecessarily prolonged periods.

## **14.3 Conclusion**

When RACF residents taking antipsychotics or benzodiazepines were followed up a year later, the majority were taking the same drug at the same dosage, contrary to guidelines which promote dose reduction and cessation. Information regarding the risks and limited benefits of antipsychotic and benzodiazepine medication appear not to be impacting the usage or review of these agents. More research is needed to establish the determinants of psychotropic prescribing in the RACF setting and to ascertain the barriers to the recommended review of these agents.

**PART THREE: DETERMINANTS OF PSYCHOTROPIC  
MEDICATION USE IN RACFs:**

**A qualitative study**

## CHAPTER FIFTEEN: INTRODUCTION

### A QUALITATIVE STUDY OF PSYCHOTROPIC PRESCRIBING IN TASMANIAN RACFS

#### **15.1 The determinants of psychotropic prescribing**

A British nursing study examining psychotropic prevalence in RACFs stated that the reasons for the excessively high use of these agents were:

*‘Primarily due to a failure of doctors to consider alternatives and a failure to review the medication.’*<sup>398</sup>

Is the answer that simple? Are doctors generally to blame for the high rate of psychotropic prescribing in RACFs purely because they fail to consider non-drug treatment of behavioural and psychological symptoms and basically don’t review these medications? In their defence, doctors would probably argue that they are often pressured by either staff, residents or relatives to prescribe something to ‘settle the patient down’ and that they encounter resistance when they attempt to alter psychotropic medication.<sup>491,492</sup> It could also be debated that as Australian accredited pharmacists are funded to review the medications of RACF residents, shouldn’t they shoulder some of the responsibility for inadequate psychotropic review practice?<sup>46</sup>

It is difficult to know which professional group influences psychotropic medication use and review to the greatest extent, primarily because there are very few research studies that have sought to gain an in-depth understanding as to why psychotropic medications are prescribed in RACFs, who initiates them and what factors account for the lack of review of these agents.

Many researchers from various disciplines have pursued statistical associations between resident, facility and other factors in order to explain the high use of psychotropic agents.<sup>83,458,463,493</sup> Yet, quantitative investigations into the reasons why many residents in RACFs take antipsychotic and anxiolytic/hypnotic medications have proved inconclusive and contradictory. There seems to be little consistent relationship between prevalence rates of these psychotropic agents and such characteristics such as age, sex, facility size and ownership.

What does appear to be a fairly consistent observation in many studies, though not all, is that rates of psychotropic prescribing increase in RACFs when nursing staff levels are low. Svarstad and Mount, for instance, reported that the level and quality of benzodiazepine prescribing in U.S. RACFs was influenced by nurse staffing levels, with lower levels of staffing resulting in higher rates of long-term benzodiazepine use.<sup>412</sup> Likewise, Kim and Whall found that residents in RACFs with more registered nurses were less likely to use psychotropic medication.<sup>463</sup> However, there are some studies that have not found a link between staffing

levels and psychotropic use. In a study of 23 Norwegian RACFs, psychotropic drug patterns were not significantly influenced by the staffing levels at each facility.<sup>494</sup> What does appear to be important when it comes to psychotropic use is that all studies report a wide variation in psychotropic rates of use between facilities.

Extensive variation between psychotropic prescribing rates between facilities was also observed in the first stage of this thesis. This disparity in prescribing practice between institutions provides evidence that other factors, most probably related to the RACFs themselves, and the individuals and health service providers working within them, must play a major role in determining the utilisation of psychotropic medication in this setting.

## **15.2 Prescribing decisions**

Prescribing is said to be one of the most common medical interventions experienced by older residents in RACFs, yet, it is well acknowledged that quality is often poor, with the overuse of many medications, underuse of alternate therapies and a general lack of review practice.<sup>491,495</sup> Many justifications have been made to account for the poor quality and high level of psychotropic prescribing, including inadequate education for health professionals, staffing shortages, limited promotion of 'good practice' guidelines and the lack of funding for aged care facilities in general. Other researchers allude to deeper 'contextual forces' within RACFs and the staff working in them which influence psychotropic prescribing, and that these need to be understood before real changes in practice can be made.<sup>496</sup>

Prescribing decisions, especially those made regarding older people in residential aged care, are not clear cut. They are complex because they involve clinical, pharmacokinetic and psychosocial factors.<sup>497</sup> Although doctors are legally obliged to sign the prescriptions, there are many influences on their prescribing habits and factors that affect whether they actually prescribe pharmacological treatment or not; and in the event they do, what medication, dose and duration of treatment they prescribe.

## **15.3 Factors influencing prescribing in RACFs**

To gain further insight into what 'drives' prescribing, it is important to examine some of the distinct factors that may influence prescribing practice in this setting. Hughes *et al.* classified these as either 'external', factors that have been imposed on the RACF by outside agencies (e.g. accreditation standards and guardianship regulation), or 'internal', which are those factors that occur within the RACF, including the characteristics of the resident, relatives, nursing staff, GP and pharmacist characteristics, and RACF attributes (e.g. staffing and RACF size).<sup>391</sup>

### **15.3.1 External factors**

An example of an external factor that has the potential to influence psychotropic prescribing practice is regulation. In the U.S., OBRA-87 legislation and the related interpretative guidelines state that psychotropic drugs must only be used to treat a specific medical condition and use should be monitored closely and reviewed regularly, with dose reductions mandated quarterly for most agents.<sup>408,409</sup> These regulations are overseen by pharmacists who are required to review all residents' medication on a monthly basis, and are enforced by annual surveyor inspections.<sup>391</sup> Although these regulations initially led to a marked reduction in antipsychotic use, they did not appear to reduce the level of benzodiazepine prescribing in U.S. RACFs.<sup>498,499</sup> Recent studies have suggested that antipsychotic prevalence rates have now returned to pre-OBRA-87 levels, leading to some speculation that a firm regulatory approach may not be the most effective method of ensuring appropriate psychotropic prescribing.<sup>498</sup>

In Australia, a different approach to ensuring effective medication use in RACFs has been taken, underpinned by the 'National Strategy for Quality Use of Medicines' policy.<sup>500</sup> In 2002, partly in response to concerns regarding RACF prescribing raised by Professor Snowdon's Sydney study and subsequent federal and NSW enquiries into the use of psychotropic medication in RACFs, the APAC produced national 'Guidelines for Medication Management in Aged Care Facilities'. These Guidelines were incorporated into accreditation standards and linked to RACF funding.<sup>38,49</sup> Though one of the accreditation standards directly relates to medication management, the standards themselves do not specify indications, recommended doses and durations of psychotropic treatment; and mandatory audits of psychotropic use are not conducted routinely, unlike in the U.S.

The Australian Pharmaceutical Benefits Scheme (PBS) may also exert an external influence on prescribing. The 'Pharmaceutical Benefits Schedule' lists all medications that are subsidised by the government.<sup>102</sup> However, drug listings can be conditional: Certain medications can only be prescribed to patients with specific indications and these restrictions may be enforced by the need to obtain individual approval or 'authority', usually by phone. King and Roberts, in a cross-sectional study of 15 Australian RACFs, claimed that the level of PBS restriction and the proportion of residents prescribed a potentially inappropriate medication (PIM), many of which were psychotropic agents were highly correlated.<sup>440</sup> To justify this claim, they provided evidence that several Beers-listed PIMs such as barbiturates, not subsidised on the PBS, were rarely prescribed, and that authority prescriptions for many PIMs were rarely requested.<sup>440</sup>

It could be argued in this case, though, that the majority of prescribers would be unlikely to prescribe superseded medication such as barbiturates. The fact that these outmoded medications are not subsidised by the PBS is not what limits prescribing. The availability of

safer alternatives such as benzodiazepines, in all probability, is why these older PIMs are not prescribed any longer. Another argument to counter King and Roberts' conclusion that the PBS effectively restricts PIM prescribing is related to the high usage of antipsychotics in older people with dementia. King and Roberts used the 2003 Beers criteria to classify PIM use, which, as discussed in stage one in this thesis, does not factor in antipsychotic use. Thus, this area of RACF psychotropic prescribing was not examined in relation to PBS coverage.

The only atypical antipsychotic in Australia subsidised for the treatment of BPSD is risperidone, and only then after non-pharmacological strategies have been trialled.<sup>102</sup> All other atypical antipsychotic agents require an authority prescription and should, legally, be subsidised solely for the treatment of schizophrenia and related disorders. In spite of this restriction, Australian RACF prevalence studies have shown the use of olanzapine and other 'authority restricted' atypical antipsychotic agents to be widespread.<sup>417</sup> It appears as if these antipsychotic medications are subsidised by the PBS as well, despite the fact that they are only supposed to be used for people with schizophrenia and related disorders. A recent analysis of PBS data has drawn attention to a large peak in subsidised use of these atypical antipsychotics in older people, particularly females aged over 80 years.<sup>101</sup> Furthermore, the use of these authority-required antipsychotics is acknowledged in the Royal Australian and New Zealand College of Psychiatry (RANZP) 'practice guideline for the use of antipsychotic medications to treat BPSD' and recommendations are provided for their use to treat people with dementia.<sup>94</sup> Thus, it appears as if the PBS authority restrictions on atypical antipsychotics do not impact the prescribing of these agents in RACFs to a significant degree.

Although regulation and reimbursement policies may influence prescribing to a certain extent, high levels of psychotropic use have continued to be reported since their introduction. Thus, other 'internal' factors appear to exert a greater influence on prescribing practice.

### **15.3.2 Internal factors**

#### *15.3.2.1 Resident factors*

Of all factors, the clinical need of the resident, ideally, should be the major driver for prescribing decisions.<sup>391</sup> However, some argue that in the RACF context, control of difficult and disruptive behavioural symptoms is the main reason for prescribing psychotropic medication, rather than a genuine clinical need for such medication in many cases.<sup>62,501</sup> There is considerable debate over whether the 'clinical need' of a resident encompasses the treatment of certain behavioural symptoms such as 'wandering' or 'calling out'. These types of behavioural symptoms, although disruptive to staff, relatives and other residents, may not cause significant distress to the resident themselves. As psychotropic medications are associated with modest benefit and significant risks in older frail residents of RACFs, professional guidelines

emphasize that antipsychotic agents should only be prescribed when there is a serious degree of distress or risk of harm to the resident, or risk of harm to other residents and their caregivers.<sup>96</sup> Likewise, benzodiazepines should be prescribed when non-drug interventions have failed, for time-limited periods and long term users should be encouraged to reduce use.<sup>95</sup> Whether professional guidelines significantly influence prescribing decisions in RACFs when psychotropic medications are initiated and reviewed for residents with challenging psychological and behavioural symptoms is unknown.

An influence on the prescribing of psychotropic medication that is commonly raised, particularly in regards to benzodiazepine prescribing, is that of resident demand.<sup>502</sup> In one survey conducted in the U.S. such ‘patient demand’ was cited by 46% of prescribers as their primary reason for prescribing medications of ‘dubious efficacy’.<sup>503</sup> In another U.S. RACF study, nursing staff reported that they had received a direct request for a hypnotic benzodiazepine medication from 24% of their residents in the month prior to the study.<sup>462</sup>

In the residential aged care setting there is increasing emphasis on ‘resident-centred care’ where the needs of the resident are recognised as being paramount and individuals are encouraged to be actively involved in decisions about their medical care.<sup>491</sup> As part of this ‘resident-centred’ philosophy the resident should be able to exercise control and choice about the medications they are prescribed.<sup>62</sup> Prescribers and nursing staff may contend that because residents request these medications they are ultimately participating in their treatment decisions; therefore, the RACF is facilitating a ‘resident-centred’ approach by providing the medication for them. However, to fully participate in shared-decision making a resident needs to make ‘informed decisions’, therefore full information should be provided to them about the risks and benefits associated with a particular treatment and they should also be counselled about alternative treatment options. Whether this information is routinely provided to residents of RACF before a psychotropic medication is prescribed is largely speculative as there is limited research in this area. However, there is evidence that older people in the community are only provided with limited information about the side effects and alternative treatment options to benzodiazepine treatment. In a qualitative study that examined the views of 28 GPs and 23 older benzodiazepine users in Queensland, only one GP suggested that patients try non-pharmacological strategies. Users also felt there was a greater need for GPs to discuss potential adverse consequences of benzodiazepine use before they prescribed them. Relevantly, users also reported that their pharmacist gave limited, if any, information about benzodiazepines when dispensing these agents.<sup>504</sup>

The ‘resident demand’ factor may not play as important a part in many prescribing decisions regarding antipsychotic and benzodiazepine medications when used to manage BPSD in RACFs. This is because many patients with these types of behavioural symptoms often lack



the capacity to participate in therapeutic decisions; therefore their ‘enduring guardian’ is legally called upon to make these treatment decisions on their behalf.

#### *15.3.2.2 Relative and carer factors*

In a U.K. discussion paper published in 2008 on the use of psychotropic agents in RACFs, Hughes acknowledged that there was a ‘*dearth of information*’ regarding the views and experiences of relatives and carers of residents on the use of psychotropic medication to manage behavioural symptoms in the aged care setting and that this was an important issue for further research.<sup>62</sup>

In Australia, when a resident is unable to participate in decisions about their medical treatment, a family member or a carer is usually appointed as an ‘enduring guardian’ of the resident.<sup>505</sup> ‘Guardianship Legislation’ provides the legal framework for obtaining consent and is aimed at ensuring that residents are not deprived of medical treatment because they lack capacity.<sup>506</sup> The legislation is also aimed at ensuring that consent is obtained before medications are initiated or altered. Thus, it could be assumed that ‘enduring guardians’ of RACF resident would influence psychotropic prescribing to a large extent.

In a report prepared for the National Ageing Research Institute in 2005, Black and Haralambous reported that one of the barriers to implementing ‘restraint-free’ care in RACFs was the families’ reluctance to remove restraints for fear that the resident’s safety would be compromised.<sup>507</sup> These researchers acknowledged that family members would often express concern about proposed changes to psychotropic medications for fear that their relative would be hurt.<sup>507</sup> This observation is in line with a U.S. discussion paper on the challenges to the use of non-pharmacological interventions in RACFs, where nursing staff reported that some family members wanted a resident to be ‘medicated’ for his or her own protection and were resistant towards any suggestions to reduce doses or trial residents without medication.<sup>508</sup> This reluctance to alter psychotropic medication may be due to a relative’s implicit belief in the effectiveness of pharmacological treatment, but also may indicate a lack of awareness about side effects associated with their use. Relatives appear to be informed about the expected benefits of the medication but not the risks. In a recent Dutch study, based in 23 RACFs, relatives, nurses and the GPs of residents recently started on antipsychotic treatment were interviewed. Interestingly, relatives were found to have higher expectations of antipsychotic treatment than both GPs and nursing staff. In addition, the family members reported that they felt insufficiently informed about the side effects of antipsychotic treatment in 44% of cases.<sup>509</sup> The results of this survey raise questions about how involved or informed the family or carers are when prescribing decisions are made about psychotropic medications in RACFs.

### *15.3.2.3 GP factors*

All prescribers have attitudes and beliefs which influence their prescribing behaviour.<sup>391</sup> At one level these beliefs relate to the perceived effectiveness of medication and the most appropriate strategy to treat certain conditions. Ideally, such GP beliefs are evidence-based and guided by education, professional guidelines and published peer-reviewed research. However, it has been observed that many GPs attending RACFs have limited education on geriatric mental health, particularly in pharmacotherapy.<sup>510</sup> In a recent survey involving 132 Israeli GPs providing medical services to RACFs, over a quarter of GPs had not participated in any geriatric medical education at all. Furthermore, when the Israeli GPs were asked to rank the topics they thought were most needed for continued medical education, they ranked the 'use of medications' as foremost, ahead of infectious diseases, cardiac conditions and depression.<sup>510</sup>

Another important source of information that may influence prescribing is advice from specialists, other allied health professionals and patient support groups. In a study of 12 U.S. RACFs more frequent consultation with psychiatrists was associated with a higher quality of psychotropic prescribing.<sup>511</sup> However, many GPs attending RACFs have shown reluctance to refer residents to psychogeriatric services, psychiatrists or counselling services.<sup>512</sup> This 'reticence to refer' was demonstrated in an Australian survey of 436 GPs when they were asked to respond to a scenario regarding a patient with suspected dementia. Less than 10% of the respondents referred patients to counsellors, psychiatrists or associations such as Alzheimer's Australia.<sup>513</sup> The low rate of referral of older people by GPs to psychiatric services has been confirmed in an analysis of Medicare billings which showed that, per capita, younger adults received 3.5 times the level of psychiatric services that people over 74 years of age received.<sup>34</sup>

GPs' overall perception of older people and ageing is also believed to influence their prescribing.<sup>85</sup> In a qualitative study of 12 Canadian GPs responsible for the medical care of a large population of older people, the unanimous perception of the ageing process was found to be very negative and GPs associated ageing with a high level of psychological suffering.<sup>514</sup> All of the GPs felt that benzodiazepines they prescribed were helping their patients to remain functional. In addition, most of the Canadian GPs did not observe side effects associated with benzodiazepine use, nor did they recall patients reporting adverse effects to them. Many of these GPs expressed limited confidence in non-pharmacological strategies, believing that they were ineffective for older people. Their decision to prescribe psychotropic medication was often seen as the most effective way to alleviate the suffering of the patient.<sup>514</sup>

Interestingly, in a qualitative study where eight old age psychiatrists in the U.K. were interviewed about factors influencing psychotropic prescribing, many felt that ageist attitudes of GPs and nursing staff were the root cause of much of the high level of inappropriate use.<sup>492</sup> Unlike the GP group in this study, all of the old age psychiatrists felt that non-pharmacological

approaches could be effective, but that the main barrier to use was that these approaches were often time consuming and there was a lack of resources to conduct them.<sup>492</sup>

There are other factors that have been reported to account for inappropriate psychotropic prescribing by GPs in RACFs. These include residents having multiple prescribers over time and GPs being reluctant to alter medications other practitioners had started.<sup>496</sup> Further, there appears to be a lack of agreement among GPs over the interpretation of what is and is not inappropriate psychotropic prescribing<sup>89</sup> and the guidelines are perceived to be somewhat contradictory.<sup>515</sup> For instance the RACGP guidelines for the use of benzodiazepines specify that long term use should be avoided but at a later stage they state that regular users should be switched over to the long-acting agent diazepam.<sup>95,515</sup> The prohibitive cost of counselling and psychological services and the perceived inability to actually change poor prescribing practices in RACFs are other GP-related justifications given for inadequate psychotropic prescribing practice. These factors are summarised below in Table 48.<sup>85,314,357</sup>

**Table 48: GP-related factors to explain inappropriate psychotropic medication use**<sup>85,314,357</sup>

Difficulties changing medication initiated by another GP or specialist
The number of prescribers involved in RACF care
Cost issues related to non-pharmacological options, including counselling
Feelings of powerlessness to effect the overall issue of inappropriate psychotropic prescribing

#### *15.3.2.4 Nursing staff factors*

Nurses play a key role in medication management in RACFs. Registered nurses (RNs) and certified enrolled nurses (ENs) have the responsibility of preparing, checking and administering medication.<sup>516</sup> As nursing staff spend more time interacting with and observing residents than other health professionals involved in resident care, they are said to be in the ideal position to assess behaviour, monitor effectiveness of treatment and detect adverse effects of medication.<sup>516,517</sup> An important question to consider is do they influence prescribing as well?

One of the most common excuses given by GPs for prescribing psychotropic agents is that the RACF nursing staff ‘pressure’ them into prescribing them. In a descriptive narrative study, a GP working in a RACF for over ten years claimed that:

*‘a typical scenario was for a nurse to call a GP to report that a resident was agitated.....some GPs accepted a nurse’s assessment without question and initiated psychotropic drugs’.*<sup>496</sup>

Voyer *et al*’s 2003 discussion paper on geriatric mental health nursing care considered that nurses ‘become gatekeepers for the initiation of psychotropic medication’, and they go further

to state that *'the influence of the nurse over the GP prescription pattern should not be minimized.'*<sup>518</sup>

Several researchers have shown that nurses in RACFs play an important part when some medications are initiated. For example, a Canadian qualitative study found that nurses played the central role in the decision to prescribe antibiotics in residents with asymptomatic bacteriuria, despite the fact that there is limited evidence of benefit of antibiotic treatment for this condition in older people.<sup>392</sup> Likewise, a study in Norway reported that analgesic use was significantly associated with nurse opinion regarding residents' pain.<sup>519</sup> In a more detailed study in Northern Ireland investigating the management of urinary tract infections (UTIs) in RACFs, the decision whether or not to treat varied according to the nurses' opinion. Most GPs reported that they usually accepted the nurses' assessment of the resident by phone, especially out of hours, and also admitted they would rarely visit a resident in relation to a UTI.<sup>393</sup> Although, there are anecdotal reports that many GPs rely on the nurses' assessment of challenging behaviour and order psychotropic medication by phone, there are few published studies to have evaluated processes by which psychotropic medications are initiated or altered in the residential aged care setting.

Evidence of the strong influence that nursing staff have on psychotropic use comes from a study conducted in 12 Danish RACFs, involving 288 residents. As part of the study all the residents were assessed for psychiatric disorders using standardised scales. At the same time, nursing staff were asked to identify and classify those residents they thought suffered from a mental health disorder. In the multivariate analysis, the staff assessment of the residents' mental health was a key determinant for the use of all types of psychotropic agents, whereas a mental health diagnosis using standardised scales only determined the use of antipsychotics. The researchers concluded that nursing staff perception of mental illness had a greater impact on psychotropic prescribing than standardised clinical criteria.<sup>520</sup>

If nursing staff play an important role in the assessment and management of behavioural symptoms, it is important to consider do nurses want this responsibility and determine if they are adequately trained to perform this role? These exact questions were addressed in a U.S. survey of 314 RACF nursing staff. Over half of the participants perceived themselves to be already involved in the decision-making process regarding the psychopharmacological treatment of residents, and 89% wanted even greater involvement. Yet, in the same survey, the majority of nursing staff stated that in-service courses on behavioural management were currently inadequate and they needed additional training on the clinical effectiveness and side effects of psychotropic drugs.<sup>521</sup>

In Australia, aged care workers with formal nursing qualifications mostly come from a background of hospital nursing, yet the bulk of hands-on-care is provided by staff with few or

no formal qualifications.<sup>30</sup> The training provided to these staff about mental health is often minimal. According to a 1997 survey of nursing staff from 98 randomly selected Australian RACFs, less than half (48%) had attended a course or seminar related to dementia during the preceding 12 months.<sup>30</sup> In terms of specific psychotropic knowledge, when an American research group surveyed 67 RNs in 4 RACFs in 1988 to ascertain the level of antipsychotic knowledge, they found that a third failed to identify common side effects, only 30% associated movement problems with antipsychotic use, and 22% of the nurses incorrectly believed that haloperidol, the most common antipsychotic agent at the time, was used to treat depression. Only 27% of the nurses surveyed were satisfied with the education they had received regarding antipsychotic treatment.<sup>522</sup> Though quite concerning, it should be recognised that this U.S. study was performed over 20 years ago, before OBRA-87 legislation was enacted. Nursing practice and educational provision related to psychotropic use may have changed significantly since that time. It is difficult to gauge the extent of mental health knowledge among nursing staff in Australian RACFs at the present time, with a recent review on this topic noting there is limited research in this area.<sup>523</sup>

Like GPs, the overall perceptions of older people and ageing held by nursing staff may also influence prescribing decisions. There is some evidence that many nurses hold stereotypical views about older people, such as older people are ‘cantankerous, irascible, rascallions and complaining’.<sup>524</sup> These views may impact on the quality of care provided for older people, of which prescribing plays an important part. The way nurses perceive residents with dementia, in particular, has been shown to impact the care these residents receive.<sup>525</sup> Positive attitudes that focus on residents’ abilities and what they ‘can do’, have been associated with ‘resident-centred care’, while negative attitudes that focus on the patient’s deficits appear to be linked to inadequate care.<sup>525,526</sup> Relevantly, positive attitudes toward residents with dementia have been shown to be linked with increased professional geriatric education. In a recent Norwegian study based in 14 RACFs, those nurses with specialised training in geriatrics, psychiatry or dementia care had significantly greater ‘positive attitude’ aptitudes ( $P < 0.04$ ) compared to nurses without these qualifications.<sup>525</sup>

#### *15.3.2.5 Pharmacist factors*

Accredited pharmacists in Australia have been providing medication review services to RACFs for over ten years. These RMMR services were introduced in 1998 and were later extended in 2007 to include ‘Collaborative RMMRs’ where there is greater interaction between the GP and pharmacist.<sup>49</sup> One of the principal justifications for introducing RMMRs to residential aged care was to address the high level of psychotropic prescribing.<sup>46</sup> However, the overall impact of the current Australian RMMR program on psychotropic prescribing has not been evaluated to date,

although it should be acknowledged that Professor Snowdon *et al* did attribute some of the reduction in psychotropic use in his series of follow-up Sydney RACF studies to the effect of pharmacist medication review services.<sup>395</sup>

The GP and pharmacist are said to have complementary roles in RACFs in regards to medication management, with a common basis and objectives.<sup>527</sup> GPs seek, analyse and act on medically relevant information in order to diagnose and to prescribe, whereas pharmacists recognise, evaluate and report information related to medications, including their potential benefits, documented efficacy and suspected adverse effects in order to monitor and review.<sup>527</sup> Through effective collaboration, it is theorised that the GP and pharmacist can improve therapeutic outcomes and reduce medication-related problems. In a similar fashion, the pharmacist and nursing staff can also work collaboratively. The pharmacist can ensure that the nursing staff are familiar with professional guidance related to the use of medications, that they are mindful of potential adverse effects and monitor residents for these signs.<sup>527</sup>

A question that is largely unexplored is do pharmacists exert a significant effect on psychotropic prescribing? Dr Lori Daiello, a U.S. psychopharmacist, lists a wide range of roles for pharmacists in RACF psychogeriatric care which include:

- Minimising and recognising drug-related causes of cognitive impairment
- Promoting the use of non-pharmacological management
- Monitoring for side effects of psychotropic medication
- Recommending dosage reduction and review of psychotropic agents
- Monitoring treatment efficacy in people with BPSD
- Assisting with quality assurance programs
- Education of the nursing staff and their families.<sup>528</sup>

It could be argued that if pharmacists were performing all these activities in RACFs then they must influence psychotropic prescribing practice to a considerable degree. Whether Australian pharmacists performing RMMRs, or pharmacists contracted to provide associated QUM services, fulfil these roles has not been evaluated to date, thus the influence of pharmacists on psychotropic medication utilisation in RACFs is largely unknown.

### **15.3.3 RACF organisational culture**

While many external and internal factors impact the rate and appropriateness of psychotropic prescribing in RACFs, none of them, either individually or collectively, provides an adequate

explanation for the poor quality of prescribing.<sup>391</sup> One Australian research team, led by a pharmacist, Professor Roberts, declared that '*RACF culture appears to influence prescribing*'.<sup>529</sup>

RACF culture can be more broadly classified as an example of 'organisational culture'. Davies *et al.* described an organisation as a 'mini-society', an organic social entity with its own values and processes.<sup>530</sup> Although there is debate over the precise meaning of the term 'organisational culture', most definitions recognise the social construct of the phenomenon, locate its evolution in the adoption of normative beliefs and values and see its expression in terms of patterns of behaviour.<sup>391</sup>

Researchers have only recently attempted to determine associations between the organisational culture of RACFs and psychotropic prescribing practice. In a qualitative study of 6 Northern Irish RACFs, nursing and administrative staff were interviewed in depth about psychotropic prescribing practice. Marked differences emerged among the facilities in their treatment culture. Those RACFs with a resident-centred philosophy tended to use less psychotropic medication, and reported they would try to determine exactly why a resident was agitated before using medication as a 'last resort'. In contrast, those RACFs with a high proportion of residents taking psychotropic medication did not indicate that they would try to identify causes and implement non-drug methods first-line to manage a resident with agitation.<sup>531</sup>

Another recent qualitative study involved nursing staff from 9 English RACFs. The researchers were able to categorise the RACFs into three groups according to their predominant approach to care. Three of the facilities classified as adopting a 'bio-psychosocial approach' supported the use non-pharmacological treatment to manage the behaviour of their residents, whereas those 4 RACFs who described elements of 'malignant social psychology' (i.e. viewed dementia as an incurable disease for which nothing can be done) were characterised by their high use of psychotropic drug therapy.<sup>526</sup> There are no known Australian studies to have sought associations between the perceived organisational culture of RACFs and their prescribing practice.

#### **15.4 'Chemical restraint'**

It is difficult to discuss the high prevalence and often potentially inappropriate use of psychotropic medication in RACFs without consideration of the issue of 'chemical restraint'. There has been some published research in Australia regarding restraint use in the RACF environment, however, much of the research has considered the use of 'physical restraint', such as vests, straps and bed rails, to modify behaviour, as opposed to the use of 'chemical restraint'.<sup>532</sup>

As might be expected, there is no universal definition of what is considered to be ‘chemical restraint’. Mott *et al.* define chemical constraint as:

*“Both deliberate and incidental use of pharmaceutical products to control behaviour and/or restrict freedom of movement, but which is not required to treat a medically identified condition.”*<sup>533</sup>

The research evidence is limited on the use of ‘chemical restraints’ in Australian RACFs.<sup>507</sup> This is obviously a contentious and complex issue and relates to many factors. The present research did not seek to establish whether psychotropic medications were prescribed and used purposively to sedate residents for the convenience of nurses, allied health staff, relatives or the facility itself; the overarching aim was to gain a greater understanding around psychotropic use in RACFs.

### **15.5 Key research questions**

Quantitative analysis was employed to answer the first two research thesis questions; ‘what psychotropic medications are prescribed’, and ‘what is the extent of review of these medications?’ It was observed that more than half of all RACF residents were taking antipsychotic and benzodiazepine medications, with a third taking two or more of these agents. The use of benzodiazepines in Tasmanian RACFs was approximately three times higher than Central Sydney RACFs in the same timeframe. Furthermore, there were many potentially inappropriate psychotropic medications utilised, including high rates of cholinergic antidepressant and long-acting benzodiazepine use, high dosages and prescribing without recording a psychiatric indication. Furthermore, the review practice of psychotropic medications, like in many other RACF studies, was inadequate.

In order to understand why these medications are used so extensively and why residents often remain on these drugs for extended periods three key questions need to be answered:

- Why are antipsychotics and benzodiazepines used so extensively in RACFs?
- What are the barriers to the review of psychotropic medication?
- What are the roles of GPs, nursing staff, pharmacists and the resident’s family when psychotropic medications are initiated and reviewed?

Not only is this information vital for our understanding of Tasmanian RACF psychotropic utilisation; it is also necessary to shape the main intervention project aimed at reducing inappropriate psychotropic use in this setting.



## CHAPTER SIXTEEN: METHODOLOGY

### A QUALITATIVE STUDY OF PSYCHOTROPIC PRESCRIBING IN TASMANIAN RACFs:

#### **16.1 Qualitative research methodology**

Much of the prescribing of antipsychotic and benzodiazepine medication in RACFs has been shown to be excessive, inappropriate, inadequately monitored and infrequently reviewed.<sup>90,91,422,423</sup> In an attempt to explain the poor quality of psychotropic prescribing many researchers have conducted quantitative studies, similar to the initial prevalence study in the first stage of this thesis, to find associations between rates of psychotropic use and demographic and facility variables in RACFs.<sup>92,422,463,534</sup> Following statistical analysis, the conclusions from different studies are often contradictory, which may signify that there are other determinants that influence psychotropic use. As some of these influences are difficult to quantify, alternative research approaches are required to attain a greater depth of understanding of the determinants of psychotropic use.

Qualitative research methodologies allow researchers to address different kinds of research questions than those addressed by quantitative methods. These types of approaches focus on meanings and understanding of experience, rather than what can be reduced to quantitative measures.<sup>497</sup> Expressed in terms of prescribing research, quantitative methodologies tell us exactly what is prescribed and test variables to establish if they affect prescribing. Qualitative methodologies, on the other hand, approach the research questions from a different perspective. For instance, qualitative research may aim to explain how the decision to prescribe a particular drug is reached, determine the influences on a GP's prescribing and establish the various factors affecting the decision to prescribe.<sup>497</sup>

There are substantial differences between quantitative and qualitative research. Qualitative methodologies collect data in the form of talk, observations, visual images and documents.<sup>535</sup> Behaviours, understandings, and actions are not measured and statistically analysed as in quantitative research. Instead, qualitative researchers produce written descriptions and explanations of the phenomena recalled or observed.<sup>535</sup> In quantitative research the researcher is objective and independent, whereas in qualitative research, the observer is recognised as a participant whose own views and values will, to some degree, impact on the data collected.<sup>536</sup>

##### **16.1.1 Types of qualitative methodologies**

A thoughtful and appropriate methodology is necessary for a rigorous qualitative project.<sup>535</sup> A methodology describes and justifies why particular methods of data collection and analysis have

been selected and are appropriate. Most qualitative research projects justify their methodology by being located within a particular theoretical approach. One such example of a theoretical approach is 'ethnography' which aims to study and describe a culture primarily through observation.<sup>535</sup> Another theoretical approach gaining popularity in the health care setting is termed 'action research' where participants and researchers work together with the aim of changing or improving a situation.<sup>537</sup>

### **16.1.2 Grounded theory**

A popular theoretical approach for a qualitative methodology is termed 'symbolic interactionism' which assumes that human action results from the meanings which are continually 'created, recreated and modified in interaction'.<sup>535</sup> The most direct link with symbolic interactionism is 'grounded theory'.<sup>535</sup> Although there is much debate about what is actually meant by the term grounded theory, the method is one of the most commonly employed qualitative methodological approaches in health research. With its origins in sociology, grounded theory emphasises the importance of developing an understanding of human behaviour through a process of discovery and induction rather than from the more traditional quantitative research process of hypothesis testing and deduction.<sup>538</sup> Expressed simply, a grounded theory approach provides health researchers a means of generating theories 'grounded' in the realities of actual clinical practice.<sup>538</sup>

Essentially, grounded theory attempts to derive theories from a detailed systematic analysis of the patterns, themes, and common categories uncovered in interviews, observations and documents.<sup>536</sup> The focus of this approach is on the meanings and interpretations of research participants emerging from their stories and narratives.<sup>535</sup> The key inductive principle of grounded theory is that data is initially collected in the absence of firm hypotheses, which are subsequently derived from systematic analysis of the data. Continued data collection yields refined understanding which, in turn, sharpens the focus of data collection itself.<sup>536</sup> Thus, an essential feature of the grounded theory approach is the continuous cycle of collecting and analysing data.<sup>538</sup> Another important feature of this particular qualitative approach is that the researcher must continue to collect data until no new evidence or theme appears.<sup>539</sup> This process, termed 'saturation', is one of the primary means of verification in grounded theory.<sup>540</sup> It is sometimes difficult to determine when saturation has occurred during data collection. The signals of saturation, which include repetition of information and confirmation of existing categories, are inherently pragmatic and depend upon both the empirical context and the researcher's experience and expertise.<sup>539,540</sup>

The data collected using the grounded theory approach is ‘thematically analysed’, which begins with the initial collection of data and involves identifying themes and categories, and connecting them, a process often referred to as ‘coding’.<sup>537</sup>

There are several reasons for the popularity of grounded theory in health research. Firstly, grounded theory places emphasis on the opinions and experiences of the study participants which appeals to researchers who want to learn about the phenomena under study from the perspective of research participants. Secondly, grounded theory is quite prescriptive, in that there is a clearly structured ‘how-to-do’ framework which may appeal to new researchers and particular research fields, such as pharmacy research, with backgrounds in more structured quantitative research.<sup>535</sup>

### **16.1.3 Qualitative methodology chosen for this study**

Of all the qualitative approaches, the grounded theory approach was elected as the most appropriate to answer the main research questions of stage two of this thesis. As there is a lack of published qualitative studies that examine the use of psychotropic medication in the residential care setting, the key research questions of this study are relatively unexplored. The grounded theory approach offers the potential to expose new hypotheses to explain why psychotropic medications are used, infrequently reviewed and who and what factors are influencing their use? Qualitative methodology is also relatively new to pharmacy research. Since the ‘grounded theory’ approach is one of the most structured of all the qualitative approaches, this procedural rigour may enhance the acceptability of the study in a profession currently dominated by quantitative research.

One of the key conditions for a project conducted in the grounded theory tradition is that research data is collected until ‘saturation’ is reached. In this study, however, a pre-determined number of representatives from various health professional groups associated with RACFs and relatives were selected to participate. The main reason for this methodological variation from the traditional grounded theory approach was the consideration that this qualitative study is one introductory phase of a three phase thesis whose main component was a large federally funded intervention project with strict time constraints. This meant that the amount of time available for the qualitative phase of the research was restricted. Another important constraint was the limited participation of GPs, who are very difficult to recruit.

During the initial stages of this research, an ethnographic component was proposed involving detailed observation of psychotropic medication management in RACFs. An ethnographic approach has the advantage of revealing actual practice rather than being told by participants what is happening.<sup>535</sup> This methodological approach was not pursued in this study for several reasons. Firstly, skilled focused observation requires specific training and is more

time-consuming than an interview study. Secondly, there were also ethical issues around informed consent from staff, residents and their families which made this approach potentially problematic.<sup>535</sup>

## **16.2 Data collection method**

Semi-structured interviewing was selected as the data collection method for this study as this method facilitates in-depth understanding.<sup>535</sup> One-on-one interviews are also usually readily accepted by participants. To gain a full insight into psychotropic use in RACFs, it was considered important to interview participants who were involved when these medications were prescribed, administered and reviewed; namely GPs, nursing staff (both registered and enrolled), pharmacists and to also consider the opinions and experiences of the ‘enduring guardians’ of residents.

The use of several focus groups were considered briefly for this qualitative component of the research; however, this method requires in-depth training for the facilitator, there are limitations in the number of topics that can be discussed, and there are ethical challenges related to confidentiality and anonymity that may inhibit discussion around a sensitive subject such as psychotropic use.<sup>535</sup> It was considered more appropriate for the participants to be interviewed separately, in private, so they could express their views fully and openly relate their experiences without being influenced by the other participants of a large focus group.

## **16.3 Sampling**

Sampling in qualitative research is not concerned with ensuring that the findings can be statistically generalised to the whole population. Rather, participants are selected purposely for in depth study to look for meaning, interpretations and processes.<sup>541</sup> The key objectives of this study were to gain an understanding of why psychotropic medications are used so extensively in the RACF setting and determine who influences their use and review. To this end, selection of the sample RACFs was aimed at selecting facilities that had been identified from the quantitative study in the first stage of this project of having average or higher rates of use of psychotropic medication. Two RACFs specialising in challenging behaviour and alcohol dependence were excluded from the study as the use of psychotropic medication in both facilities was very high and these particular facilities also had a high level of old age psychiatrist support; thus, neither facility was included they were not considered to represent a ‘typical’ RACF. Those RACFs with lower than average rates of psychotropic prescribing were not invited to participate as it was thought that participants from facilities with a low rate of psychotropic use would encounter difficulty recounting instances where psychotropic

medications were used. If they didn't routinely use psychotropic medications then they may be unable to assist understanding of the three key research questions.

The selection of individual participants from each facility was aimed at obtaining a sample of health professionals directly responsible with residents' medication therapy and relatives who are legally responsible for their medical care. Six participants were recruited from each of the five sample RACFs; one registered nurse, one enrolled nurse, one GP, one pharmacist and two relatives of residents with challenging behaviour. Only the 'enduring guardian' or designated 'person responsible' for a resident, usually a relative, was invited to participate in this study. The 'Guardianship and Administration Act' of 1995 states that only these persons are legally appointed to make medical decisions on behalf of the resident - if the resident is not capable of making these decisions.<sup>505</sup>

The data collected from the sample of 30 participants contained many repeating themes, providing a rich and largely saturated data set to examine issues around psychotropic utilisation in the residential aged care setting.

The method for RACF sample selection was as follows: All twenty Hobart facilities from the first stage of the study were ranked in order of the proportion of residents taking antipsychotic and benzodiazepine medication. The five facilities with the highest prevalence of psychotropic use were sent a letter inviting them to participate in the study (the invitation letter is attached as Appendix E). At this stage, one of the RACFs approached declined participation so the next highest ranked facility, in terms of psychotropic utilisation, was sent an invitation. A meeting was then held with each of the RACF nursing managers and the researcher to outline the study fully. After this initial meeting, all RACFs approached agreed to participate.

As part of their involvement, each RACF was asked to identify one registered nurse and one enrolled nurse who would be willing to be interviewed and to provide a list of relatives who were 'enduring guardians' and attending GPs who they considered may be interested in participating in the study. Each facility was also asked to identify the pharmacists associated with medication review and/or supply. All potential participants were sent a letter, which outlined the study background, interview topics and stated that the interview would be confidential and anonymised (attached at Appendix F). It was also explained that the potential participants were under no obligation to agree to be interviewed. Once the signed consent forms were returned the participants were contacted and an interview time and place was arranged.

All ten selected nursing staff and five pharmacists sent an invitation letter agreed to be interviewed. Likewise two relatives from each home also agreed to participate; however, on the day of the interview one of the relatives was hospitalised so the RACF provided the name of another relative who was approached and subsequently agreed to participate. A total of eleven letters were sent to GPs before five of them agreed to be interviewed. Three of the GPs

approached said they were too busy to be interviewed, one said that they didn't think there was a problem with RACF prescribing so declined participation, and two advised their receptionist to inform the researcher that they were unavailable.

All 30 interviews were conducted over a 3 month period from April 2008 to July 2008.

## **16.4 The interview**

### **16.4.1 Interview Procedure**

Before the interview commenced, all participants were given a brief verbal outline of the study and a written information sheet. They were all asked if they would allow the interview to be recorded on a voice recorder. Assurances were given that the recording could be stopped at any time and that all data would be anonymised. Once full consent was confirmed, demographic details were noted for all participants and the interviews commenced. The only interviewer in this stage two study of the thesis was the researcher herself.

### **16.4.2 The interview design**

Four separate interview schedules, customised for each group, were devised to answer the main research questions of the study (see Appendices G, H, I and J). The semi-structured interview schedules consisted of open-ended questions but respondents were encouraged to talk freely. The order and wording of questions were adjusted when necessary, so that an idea could be pursued. During the course of the interviews, further questions were introduced to explore emerging themes and concepts in greater detail.<sup>537</sup>

The interview schedules were pre-piloted with a director of nursing at a dementia-specific facility in Hobart that was not involved with the study, and an experienced consultant pharmacist so that the content and progression of the questions could be evaluated and refined. Feedback was also sought from the pilot interviewees regarding the interpretation of questions and relevance of the hypothetical vignette to current practice. After the pilot transcripts were transcribed and evaluated, the schedules were refined further with the assistance of one of the supervisors who is an experienced qualitative researcher. The interview schedules for each participant group are attached as Appendices G, H, I, and J.

### **16.4.3 The interview schedule**

Topics for the interview schedule were derived from the literature review and from questions that arose during the first phase of the thesis. New topics were added as the interviews progressed and new concepts and themes emerged, consistent with a grounded theory approach.

For the health professional participants, the nursing staff, GPs and pharmacists, each interview began with an open question to *“Tell me how long you have worked in this RACF and*

*in RACFs, in general?*” The interview schedule of the health professionals included questions to evoke their experiences of residents with psychological and behavioural symptoms and how these particular symptoms were managed. Views were also elicited on issues relating to influences on the use of psychotropic medication, their opinion regarding their effectiveness and the experience of side effects with this type of medication. Health professional participants were also asked about the information sources they used to guide the use of psychotropic medications and their training on old age mental health, especially in relation to the management of challenging behaviour.

The opening question for the relatives was: *“Could you please tell me about your relative, and how long have they lived in this RACF?”* The interview schedule of the relatives included questions about the mental health conditions of the resident, how these conditions were managed and how the staff and GP at the RACF communicated issues relating to behaviour to them. Relatives were also asked about the procedure when new medications were initiated and views were sought about the effectiveness and side effects associated with drug treatment.

To counter the possibility that participants would give ‘appropriate’ responses rather than recall actual practice, participants were encouraged to provide examples of resident’s behaviour rather than be tested on individual knowledge. A case study or ‘vignette’ was also incorporated late into the interview schedules of all participants as an opportunity for participants to discuss how they would handle the hypothetical situation. By using this vignette it was hoped that differences would emerge in the way the participants managed the case study and their own opinions and experiences recounted earlier in the interview.

Each interview ended with the query if there was anything else the participant wanted to talk about and all participants were offered the opportunity to contact the interviewer if they had anything else to add or wanted to clarify any statement they had made. Only one of the participants, a relative, contacted the interviewer the day after the interview to justify and expand further on a statement they had made.

## **16.5 Reflexivity**

In qualitative research the researcher’s personal views and values will, to some degree, impact on the data collected. Thus, it is important for the researcher to avoid imposing their own assumptions on the interviewee’s account as much as possible.<sup>497</sup> To ensure a rigorous qualitative study, the researcher must reflect on their own assumptions and biases and the way they may affect the interview.<sup>535</sup> This reflexivity activity also aids future sampling, re-framing of questions and assists analysis.<sup>537</sup> To this end, memos and field-notes were written at the time of data collection and directly after each of the interviews. This data was also added during

transcription and the initial reading of each transcript so that underlying attitudes or contributions that the interviewer may have made were noted during each interview.

## **16.6 Data Analysis**

All interviews were digitally recorded and transcribed verbatim by the researcher or an experienced transcribing clerk. The interview transcripts were initially sorted into groups of nursing staff, GPs, pharmacists and ‘enduring guardians’ and analysed in these groups. Each participant was assigned a professional group-relative / numerical identifier which were ‘GP’ (General Practitioner), ‘R’ (Relative), P (Pharmacist), EN (Enrolled Nurse) and RN (Registered Nurse). As part of the overall analysis the collective analysis from each group was later compared with those of other groups.

The methodology used to analyse the transcripts used a combination of ‘content analysis’ and ‘thematic analysis’ which follow the principles of ‘grounded theory’ whereby concepts, categories and themes are identified and developed as they emerge from the interview data.<sup>541</sup> A ‘concept’ is a descriptive or explanatory idea, with a ‘category’ defined loosely as a collection of closely linked concepts.<sup>542</sup> As part of the analysis, each category was compared to other categories and/or divided into ‘sub-categories’.<sup>543</sup> A ‘theme’, on the other hand, is a central idea emerging from the data.<sup>537</sup> Concepts and categories are basically what is contained within the data but themes usually emerge later to tie the research together.<sup>543</sup>

All of the transcripts were initially checked for accuracy against the original recordings. Each of the transcripts was then read and re-read to identify the key concepts and themes, allowing the researcher to become fully immersed in the data.

At the heart of grounded theory is the process of coding pieces of text into key concepts and then collating all those that are coded in the same way into separate categories.<sup>535</sup> Content analysis was initially used whereby a set of existing codes, ‘a priori’ or ‘deductive’ codes were developed during the initial literature review of this qualitative stage of the thesis, including ‘views on non-drug management of old age mental health conditions’ and ‘extent of psychotropic medication review’ which were used in the initial coding process. Other ‘inductive codes’ were developed through the coding process itself as they emerged from the interview data and memos; for example, ‘communication between GPs and nurses’ and ‘relatives’ involvement’.<sup>541</sup>

The coding process was conducted in three steps using thematic analysis where categories were uncovered through detailed examination of the interview transcripts, though it should be noted that this process was continuous as new interviews were collected and analysed. Firstly ‘open coding’ was performed where concepts, observations and quotes from each interview were grouped into categories. These categories were subsequently broken down and elaborated



on further by the creation of subcategories, a process defined as ‘axial coding’. Finally, ‘selective coding’ was attempted by which all categories are unified around a core category, enabling the development of theories to explain the key research questions.<sup>541</sup>

As data continued to be collected and interviews were analysed, earlier interviews were re-examined and re-coded to incorporate categories and themes that emerged in later interviews. Codes were reviewed and condensed into categories and themes relevant to answer the key research questions.<sup>544</sup> Charting was also employed to ‘map’ the range of categories and themes and to find associations between themes with a view to providing explanations for the findings.<sup>545</sup>

The interview data was imported into a computer package designed to assist with qualitative data analysis (QSR NVIVO7©) by electronically organising, indexing, linking themes and retrieving the data. As another step of the analysis, a simple ‘cut and paste’ technique was used to group pertinent quotes from the transcripts together under relevant themes and categories. This ‘hands-on’ process helped refine and verify the initial coding and charting process. Finally, after the preliminary findings had been established, all the interview data was re-read to fine tune the analysis.

In this study, like other qualitative research, the results are not expressed in a quantitative format, as statistically representative groups of respondents were not interviewed.<sup>545</sup> However, simple counts have sometimes been used to provide a summary of some aspects of the analysis. The data is mostly presented in the form of commentary with relevant quotes from the transcripts that illustrate the analysis. The results and ensuing discussion have been grouped under the headings of the study key research questions. From the analysis, a hierarchy of superordinate and subordinate themes were established for each research question.

## **16.7 Ethical approval**

Ethical approval for this second stage of the thesis was granted by the Tasmania Social Sciences Human Research Ethics Committee (The ethics proposal is attached as Appendix K). Ethical considerations covered participant anonymity, consent, safe storage of taped and written data and participant support in the event that interviewees were challenged by some of the interview content. Psychological counselling was offered in the event that the interviews evoked memories and issues that the participant wanted to discuss further.

## CHAPTER SEVENTEEN: RESULTS

### A QUALITATIVE STUDY OF PSYCHOTROPIC PRESCRIBING IN TASMANIAN RACFS:

#### 17.1 Study population

##### 17.1.1 The nursing staff

All ten of the nursing staff interviewed were permanent staff and had worked in their respective RACFs for at least a year. Five of the nurses were RNs and the other five were ENs. One of the ENs was about to commence a conversion degree course to become a RN and another had recently graduated from an TAFE conversion course as an EN after working as a care assistant in the same RACF for 2 years. All the nursing staff participants were women and all came from a white European background. One of the RNs interviewed was the RACF manager with an additional postgraduate qualification in aged care nursing. Two of the RNs were in charge of ‘high care’ dementia wards. Table 49 shows the demographic details of the nursing staff:

**Table 49: Demographics of nursing staff**

Role	Age (yrs)	Time working in RACFs (yrs)	Number
RN	40-50	6	1
	50-60	5-15	3
	60-70	21	1
EN	20-30	3	1
	30-40	4-8	2
	40-50	8	1
	50-60	3	1

All of the interviews with each of the nursing staff were conducted in the RACFs during working hours. Two of the nursing staff participants asked if they could express their opinions after the interview was terminated and the tape recorder had been switched off. They wanted to talk ‘off the record’. The two nursing staff participants were from different facilities but both wanted to say what they felt without the fear that their opinions would be relayed back to ‘management’. Although, they were assured that all interviews were confidential and anonymised, they still the tape recorder switched off. This behaviour probably reflects of the sensitivity of this topic. The unrecorded views of these two participants have not been included in the present analysis.

##### 17.1.2 The GPs

Three of the GPs worked on a full-time basis and two worked 3 to 4 days a week. All of the GPs were based in a privately-owned practice surgery. Each of the GP participants said they visited

RACFs at least once a week, often more frequently, depending on the clinical status of their patients at the facility. None of the GPs had a formal qualification in geriatrics or in mental health. The demographic details of the GPs can be viewed as Table 50:

**Table 50: Demographics of the GPs**

Sex	Age (yrs)	Time working at RACFs (yrs)	Number
Male	30-40	4	1
	40-50	5-20	2
Female	30-40	3	1
	50-60	18	1

Three of the interviews were held in the participant GPs surgery and two of the interviews were conducted in the RACF.

### **17.1.3 The pharmacists**

Three of the Pharmacists were accredited to perform medication reviews for RACFs and the other two were owners of pharmacies contracted to supply medications to the facilities. These two latter pharmacists both provided medication advice, education for nursing staff and medication audits to their respective RACFs. Three of the pharmacists worked at the community pharmacy supplying the RACF and the other two pharmacists worked as independent consultant pharmacists. Table 51 displays their demographic details:

Of all the professional groups, the pharmacists were the most challenging to interview in terms of access. Two of the interviews had to be re-scheduled, and another interview was rescheduled twice due to conflicting appointments and lack of pharmacist cover. Two of the interviews were conducted in the community pharmacy but these interviews were continually interrupted. Three of the interviews were conducted at the researcher's University.

**Table 51: Demographics of the Pharmacists**

Sex	Age (yrs)	Time working in RACFs (yrs)	Number
<b>Male</b>	<b>20-30</b>	<b>4</b>	<b>1</b>
	<b>40-50</b>	<b>6</b>	<b>1</b>
	<b>50-60</b>	<b>25</b>	<b>1</b>
<b>Female</b>	<b>20-30</b>	<b>2</b>	<b>1</b>
	<b>40-50</b>	<b>8</b>	<b>1</b>

### **17.1.4 The relatives**

Fourteen relatives of residents, all of whom were 'enduring guardians', were invited to participate in the study. Thirteen relatives replied to the letter of invitation, two relatives

declined to participate and one of the relatives pulled out the day of the interview due to illness, leaving a sample of ten relatives. One of the relatives asked if their spouse could participate in the interview as his wife had largely assumed responsibility for the care of his mother. Part way through another interview, the participants daughter asked could she contribute as she could her assist her father. This meant that two of the interview transcripts included the responses of two participants. The demographic details and relative's relationship to the resident are displayed in Table 52:

**Table 52: Demographics of the enduring Guardians**

<b>Sex</b>	<b>Age (yrs)</b>	<b>Relationship to Resident</b>	<b>Number</b>
<b>Male</b>	<b>40-50</b>	<b>Son</b>	<b>1</b>
	<b>70-80</b>	<b>Son</b>	<b>1</b>
	<b>80-90</b>	<b>spouse</b>	<b>2</b>
<b>Female</b>	<b>40-50</b>	<b>sibling</b>	<b>1</b>
	<b>50-60</b>	<b>daughter</b>	<b>3</b>
	<b>70-80</b>	<b>spouse</b>	<b>2</b>

Six of the interviews were conducted in the private home of the relative/enduring guardian, two were conducted in the RACF of the relative and two interviews were held in off-site locations. Three of the relatives became quite upset throughout the interview. As a result, two of the interviews had to be halted for a short period but they were both resumed after about 5-10 minutes. All these participants were offered the opportunity to terminate the interview but each participant declined this offer, saying that they felt it was important for them to continue.

## **17.2 Interview results**

Analysis of the interview transcripts revealed a wide range of experience and opinions among the participants regarding the use and review of antipsychotic and benzodiazepine medications in RACFs. The results are presented following the order of the study questions.

The first question considered why psychotropic agents are used so extensively in RACFs. Following this, the barriers to the review of psychotropic medication were sought. The vignette of the older resident taking a antipsychotic agent was purposely used to determine the participant's response; firstly, to the behaviour of the resident, secondly, to gauge what action they would take once the resident was 'settled' and finally, how they reacted to the suggestion that the medication might be altered. The final research question attempted to establish the roles of GPs, nursing staff, pharmacists and the resident's family when psychotropic medications are initiated and reviewed.

### **17.3 Why are antipsychotics and benzodiazepines used extensively in RACFs?**

The superordinate theme that emerged to explain why antipsychotics and benzodiazepines are prescribed to residents in RACFs was ‘comfort’, a term referred to by the majority of participants interviewed. The subordinate themes were; ‘limited one-on-one time’; ‘inadequate assessment’; ‘pressure to prescribe’, ‘lack of psychotropic pharmacological knowledge’ and ‘minimisation of side effects’.

#### **17.3.1 Comfort**

There was a firm belief held by most of the nursing staff, the relatives and some of the GPs and pharmacists that psychotropic medications were required for the resident’s ‘comfort’.

*“It makes the resident obviously a lot more comfortable within themselves.”* EN2

*“I think you’ve got to manage the person and keep them as comfortable as you can.”* R1

Most participants were aware of the controversy associated with sedative use in residential aged care. One of the nursing staff felt that the use of psychotropic medication was justified because comfort should be prioritised over potential risks or the way people felt about their use.

*“Surely their comfort is the priority rather than how you and I feel about taking medications you know. They’re probably not the best thing in the world for them but surely at this stage of their life, comfort comes first.”* EN8

Many of the health professionals felt that the use of psychotropic medications was justified to improve the resident’s quality of life.

*“And you look at the quality of life of some people in RACFs and you think well if you can’t even have a decent night’s sleep.”* GP4

*“It may not be nice to medicate somebody but surely it’s far nicer to have them medicated and calm than distressed. On the whole, they seem to have a positive impact, on their life.”* EN8

However, several staff expressed a contrary view about the impact of psychotropic medication on the resident’s quality of life.

*“When you look at all the side effects of a lot of these medications, and a lot of them are just sedating medications, there’s no quality in their life left is there? I mean, even a person with dementia has some quality in their day and if they’re just a big blob in the chair because of the medication, what’s the point?”* EN10

*“She was put onto risperidone and she became a zombie. No quality of life, hardly rousable.” EN3*

Yet, in many respects it was difficult to gauge the interviewee’s true feeling about residents with dementia. As part of the interview, all the health care staff participants were asked to provide an example of a resident with challenging behaviour. Some of the health practitioners tended to group the residents with dementia together, thus de-personalising the residents to a certain extent.

*“You see a lot more problems in the afternoon usually than in the morning. Because they sundown and **dementias** get more confused as the day goes on so their behaviours often escalate in the evening, wandering and stuff.” EN8*

*“You do see some very distressing behaviours and the people that call out all the time and are obviously distressed and get very agitated and aggressive when people come near them. **They’re** very difficult in RACFs.” GP4*

Almost all of the examples of challenging behaviour recounted were associated with violent aggressive behaviour where residents were lashing out and hitting people. Not one of the health practitioners referred to the resident in a favourable or positive light throughout the interview. This may have been because they were asked to recall challenging behaviour. In contrast, many of the relatives recalled how vibrant and personable their relative used to be before their dementia set in.

The use of psychotropic medication was also rationalised for the comfort of other residents in the facility. *“You know, you can’t have somebody disrupting the rest of the people that are there.”*(R3) It should be noted that the use of psychotropic medication was rarely justified for the comfort of the nursing staff, although one of the GPs’ mentioned that *“whether there is a risk to staff or another person”*(GP5) was often factored into her decision whether or not to prescribe medication. Two of the nursing staff, one RN and one EN from two different RACFs, felt that sometimes psychotropic medications were used for the benefit of the nursing staff, but never by them, or by staff where they were working.

*“I mean it (sedative medication) shouldn’t be for us, for the staff, but certainly there have been times when I’ve known that that’s what it’s being used for, not here in Tasmania, but elsewhere.” EN2*

The participant groups differed in their response to whether they thought antipsychotic and

benzodiazepine medications were effective or not. Although most of the nurses, relatives and the two community pharmacists thought psychotropic medications were effective, very few of these respondents specified that the medications were actually effective at resolving the presenting mental health symptom, such as aggression, insomnia or anxiety. Most interpreted 'effective' to mean that the resident was more 'comfortable' or 'calm', rather than less agitated, sleeping for longer or not anxious. Some of the nursing staff referred to the 'balancing act' that nurses needed to achieve between ensuring the resident was comfortable but not over-sedated.

*"For most of them, it (sedative medication) seems to be a positive. Some are too sedated, and that's where it gets tricky trying to work out how to keep them calm enough that they're not causing problems for others and not giving them too much to just make them a zombie."* RN4

The GPs, accredited pharmacists and a few of the nursing staff and relatives, on the other hand, had a more negative opinion of the effectiveness of psychotropic agents.

*"We also tried an anxiolytic, didn't really seem to help at all so. So we stopped that and then we ended up just trying her on an anti-psychotic, but I'm somewhat sceptical whether that will be of much benefit."* GP4

*"At times I have wondered about the efficacy of any medication at all, 'cause there have been times when she (the resident) hasn't taken anything and she's been pretty much the same."* R6.

The difference in views regarding the effectiveness of these medications may be because the GPs and some of the other participants interpreted effectiveness to mean addressing the underlying mental health condition rather than viewing effectiveness to mean being 'comfortable'. One of the ENs recognised the difference between the two viewpoints.

*"The only way it helped her (the resident's) behaviour was that it sedated her and of course once the sedation wore off, her behaviours were back so none of the medications helped."* EN10

There was a marked difference between individuals, even within the same facility, over whether they felt that psychotropic medications were effective or not. This difference is clearly illustrated in the following two quotes where two of the nursing staff, one an enrolled nurse and the other a registered nurse, were talking about the same resident and her experience with diazepam, (trade name: Valium) a long-acting benzodiazepine that is categorised as inappropriate for older people.<sup>359</sup>

*“It was decided, in consultation with the Doctor, that she (the resident) would go onto valium of a morning to try and alleviate this level of anxiety. But it actually reduced her mobility ability to such a level that it became another problem, as well as the fact that she was prone to tears a lot more. It just seemed to take away any control she had left. So it was the daughter in the end who went to the GP and said I don’t think this valium’s right for mum and within a few days of mum stopping the valium she was walking again quite confidently, with a walker and she’s a lot brighter in herself and she’s not tearful.”* EN2

*“Recently she was started on diazepam and she became, she became a lot brighter and to us she didn’t seem to be more unsteady on her feet but the daughter could not accept it and still can’t and she’s been taken off that medication.”* RN1

This difference in perception about the diazepam’s effectiveness might be explained by the fact that one of the interviewees was a RN with more of an administrative ‘desk-bound’ role than the more ‘hands-on’ EN who may have had more direct contact with the resident. The EN may have had greater opportunity than the RN to directly observe the effects of the benzodiazepine agent on the behaviour and mood of the resident.

### **17.3.2 Limited one-on-one time**

All of the health professionals and many of the relatives gave many examples of non-drug strategies that the nursing staff and diversional therapists had used to manage behavioural symptoms and insomnia. Many of the nursing staff said that they preferred this type of therapy over medication, and that they often needed to be quite creative when figuring out what strategy would work with a particular resident.

*“You know once they’ve tried hot packs, a hot cuppa, change of position. Yes certainly, you know, I prefer to go that way prior to sedating, you know, to giving medication.”* RN9

*“One of the Carers who worked with dad helped a lot .... so she had him a board made just off her own bat, this big wooden board and it’s got all locks and chains and things on that they sit him and he fiddles with that and it keeps him occupied.”* R5

There was general consensus among all participants that ‘one-on-one’ time with the resident was the most effective of all the non-pharmacological strategies to manage behaviour and sleep disturbance. The effect of ‘one-on-one’ time was described by one of the nursing staff:



*“There’s nothing like a calm approach some one-on-one, removing yourself...removing the resident and going with her, him or her, and spending time with them. ... it’s just letting them know that they’re not on their own.” EN2*

Although the respondents recognised and valued ‘one-on-one’ time, they perceived that this aspect of care was in short supply due to the demands on the nursing staff. The lack of one-to-one time was sometimes thought to be a reason why psychotropic medication was required.

*“I just wished that they had the time to just be with her and calm her down, talk with her and settle her down. But of course I understood that they didn’t have enough staff to do that.” R10*

*“I often wonder whether, the psychotropic medicines that we give could be less used if we had more people on board because often we medicate because I think we haven’t got the time to spend on a one to one basis with people.” RN7*

Two of the nurses reported that the reason for not spending enough one-on-one time with residents was because they had to administer medications. So, ironically, one of the reasons residents might require medication is related to the nursing time spent giving medication.

*“Aromatherapy, hand massage, foot massage, but as the E.N., I never get time to be involved in any of that because I’m forever doing pills.” EN3*

### **17.3.3 ‘Pressure to prescribe’**

All five GPs referred to pressure exerted on them by nursing staff to manage the behavioural issues and sleep problems of the residents. One of the GPs’ and several of the nurses also felt pressure to prescribe or administer medications from relatives.

*“Every time I’m contacted for behavioural challenge, the expectation is from the Nurses is that I’ll prescribe some sort of medication.” GP3*

Two of the GPs said that they were able to manage the pressure from nurses, but in different ways.

*“I mean there is an expectation at times I think I’m a lot less prone to prescribe now for several reasons, just through experience you realise that that’s not always the answer. And secondly, as you get older and more confident you become more able to resist that pressure.” GP1*

*“The expectation doesn’t bother me, if the resident’s going off then I can give them a phone order for something, yeah.” GP3*

Three of the GPs felt that the underlying culture had changed in RACFs over time and that nursing staff were now a lot more willing to try strategies aside from psychotropic drugs to manage the behavioural symptoms of the residents.

*“I think there used to be (pressure) but I think that now at RACFs it’s regarded as part of their job to try and deal with challenging behaviour in a non-pharmacological kind of way much more.” GP4*

The GPs expressed mixed views about the pressure exerted by the relatives for them to prescribe medication. Some of the nursing staff also referred to relatives asking them to medicate their relative.

*“I can’t remember the full story but certainly the pressure, we want something done, we want mum settled.” GP4*

*“He (the husband) will often come to me and say, “can’t you give her something?” RN10*

However, four of the GPs and several of the nurses said that they felt relatives wanted less medication to be prescribed rather than pressuring doctors or nurses for more psychotropic medication.

*“Most of my experience is that you know relatives don’t want their parents, their elderly relative to be on too much medication.... rather than asking for medication.” GP5.*

There were only two instances recounted where the participants referred to residents themselves exerting pressure for medication. In both cases, the residents requested benzodiazepines for sleep.

*“The fact is that a lot of people don’t sleep and they really are fairly demanding that they would like a sedative at night.” GP4*

#### **17.3.4 ‘Inadequate assessment before prescribing’**

Most of the health professionals expressed a strong view that it was important to exclude other causes for behaviours before medication was prescribed. They referred to the need for a proper assessment so that ‘triggers’ or clinical reasons to account for the symptom could be rectified.

*“I think there’s an important issue that a lot of agitation or behavioural problems may happen due to some underlying physical cause, it’s really important to exclude a physical cause before you go starting....sedative medication or anti-psychotics or anything like that.” GP1*

*“You could try a sedative to help her sleep but you’ve really got to look at the cause of why she’s calling out and not just sedate her.” EN3*

Even though the need to carry out a full evaluation before prescribing medication was recognized, a comprehensive assessment was often unable to be carried out by the GPs themselves because they all said they had problems visiting the RACFs to see residents. There were a number of reasons to account for this, including time constraints, GP shortages and a lack of remuneration.

*“The main one really is the time constraints. I mean there’s a shortage of GPs in the community and my days are just absolutely flat out.” GP1*

*“I rarely take on a patient that isn’t mine in a RACF because, on the whole, it’s very time consuming, you get interrupted with calls to ring your work sessions all the time about RACF patients. You do an awful lot of unpaid work.” GP4*

This raised the question that if the GPs couldn’t get to the RACFs, how then did they ensure the resident was properly assessed if they were displaying a behavioural symptom? All of the doctors and most of the nursing staff commented that much of the assessment was performed via the phone.

*“I know the patients fairly well and you can manage most things over the phone.” GP2*

*“I mean risperidone or haloperidol or whatever can be ordered over the phone, I mean, if that sort of behaviour warrants it.” GP3*

There were instances recalled in the interviews where issues couldn’t be dealt with by phone and the GPs were asked to come in to see the resident at the RACF. Many of the nurses and relatives provided examples where GPs appeared to delay seeing a resident.

*“Yes I’ve had one (a GP) come this morning, I’ve been trying to get him for months and he finally came this morning.” RN9*

*“Bear in mind that the doctor only sees her once in each four to five weeks at best.” R9*

Many of the relatives experienced extreme difficulty even finding a GP to take on their relative's care in the first place. There were several explanations given by nurses to account for the lack of GP access and willingness to look after residents, aside from time and resource constraints, including the perceived low priority that some of the GPs allocated to residents.

*"Thirty seven doctors we rang before we could get anyone who would even take mum on." R1*

*"I think obviously G.P.'s are busy, but I think in some ways the elderly are not a priority, as far as patients are concerned; they're in God's waiting room." RN5*

All of the GPs said that they also relied heavily on the nursing staff to assess the behaviour of the resident. The general consensus of the health practitioners was that this was an important role of the nurses.

*"We see so little of the patient compared to the nursing staff so I rely a huge amount on that nursing staff assessment." GP1*

*"I think they rely heavily on the nursing staff that we would alert them if there was a problem, rather than them just having to come and check the resident for themselves." RN4*

Many of the GPs displayed a large degree of confidence in the assessment of the nursing staff and often assumed that all behavioural options had been exhausted and other causes had been excluded before they were asked to intervene.

*"By the time I get involved either they've tried to do all of these behavioural managements and if it's not appropriate for medication then they contact the psychogeriatrician...but if it's a result of 'we need medications to try and manage this thing' then I get involved." GP2*

*"You know, I go by the opinions of the nursing staff a lot....they're the ones that say this is just a disruptive behaviour or a problem." GP5*

When behaviours were too difficult for the nursing staff to manage, residents were usually referred to a psychogeriatrician or the dementia support team. However, like the GPs, access to these specialist services was limited. And again, issues were often managed by phone.

*"We can ring them (Dementia Support) directly and have a talk to them and they can suggest different things to see if that works." GP2*

### **17.3.5 ‘Lack of psychopharmacological knowledge’**

Despite medical staff relying on nurse assessments and the nursing staff themselves feeling they were relied upon almost exclusively to assess and manage the residents with mental health conditions, almost all of them felt that they needed additional training on dementia. Several also expressed the view that this lack of education was a potential barrier to non-pharmacological treatment.

*“I love working with dementia but I feel I don’t know enough and that gets me down a little bit.. I’d prefer to know how to help them rather than dish out pills all the time.”* EN3

One specific area that many of the nursing staff felt they needed training on was medications.

*“No training specifically (on psychotropic medications). I probably have learnt through when a patient has been ordered and I’ve learned from watching effects, looking after residents with these behaviours, but no specific training.”* EN10 (dementia wing EN)

*“I haven’t been to any formal lectures on drugs.”* (RN4 in charge of a 40 bed dementia unit)

The nurses lack of knowledge about psychotropic medication became apparent when discussing individual cases and approaches to management. As an example, there are professional guidelines consistently recommending regular trials of antipsychotic tapering and withdrawal when these agents are prescribed for older people with dementia. If problems return it is relatively easy to re-start the medication. One of the nurses asked:

*“What I’d need to know and probably haven’t found out is, with risperidone, if you take them off it, can you trial them and then put them back on it?”* RN9 (nurse in dementia wing)

Similarly, when another EN was asked generally how long a resident should be taking risperidone for challenging behaviour, she answered *“maybe the rest of her life?”* (EN10)

The lack of knowledge about medication was also evident when it came to hypnotic use.

*“I’ve got one lady who hasn’t been here all that long, was on temazepam when she came in which didn’t help. She’s now on two nitrazepam which is from the same family, they put her on mirtazapine as well, so I’ve been giving that in conjunction with the nitrazepam at about nine thirty and I think that’s, well the mirtazapine helps by giving her the drowsy feeling and the nitrazepam helps keep her asleep for the length that she needs to.”* EN3

The nurse in this case appears to sanction both treatments. However nitrazepam is a long-acting benzodiazepine that is not advised for use in older people, and the maximum recommended

dose is a half to one tablet per day. Although mirtazapine is a sedating antidepressant, this drug is not licensed or subsidised by the PBS for the treatment of sleep disturbance.<sup>119</sup> The nurse does not appear to be aware of the inappropriateness of both medications.

A lack of knowledge was also observed regarding the common side effects associated with psychotropic medication. When one EN was asked what side effects she had encountered with antipsychotic use she answered *“I have to say I haven’t been aware of what they might be, other than the person being quiet”* (EN2).

It is generally acknowledged that antipsychotic medication is not effective to treat several challenging behaviours, especially the common symptom of ‘calling out’. For this reason, this particular symptom was chosen as the primary behavioural symptom for the resident in the vignette posed to each of the health practitioners in their interview. Out of all the participants, only one accredited pharmacist with specialist mental health training picked up on the fact that antipsychotics were not indicated for ‘calling out’ behaviours. In contrast, all of the GPs said they might trial an antipsychotic after ruling out other causes and all of the nursing staff accepted the use of risperidone. One nurse suggested that benzodiazepines might be more appropriate option for the resident in the vignette even though this medication class is not indicated for BPSD.

*“I just wonder whether a dose of oxazepam might be beneficial instead of risperidone or yeah I suppose, would you try oxazepam before risperidone?”* RN9

Despite the general lack of training and limited use and application of professional guidance for psychotropic use in the health professionals, the relatives displayed implicit faith in the knowledge of the GPs and staff who they often described as ‘the experts’.

*“As far as medication goes, I wouldn’t know. I feel I couldn’t suggest anything because I wouldn’t have a clue. So I’ve got to leave it to the experts to do their job.”* R7

#### **17.3.6 ‘Minimisation of Side Effects’**

One of the aspects of psychotropic prescribing that might be expected to impact psychotropic use is the adverse effects that these agents might cause, especially in the frail elder population residing in RACFs. Most of the participants could recall instances where the medication had adversely affected residents.

*“I’ve seen residents with challenging behaviours get a whole new medication regime and then they can’t walk because of the effects of the medication.”* EN6

*“I can recall a case of elevated blood sugar levels in someone on olanzapine. Risperidone, just totally zonked them out, yes I have seen serotonergic affects from some of the drugs.” P5*

However, many of the health professionals expressed doubts about whether some of the side effects might actually be due to the dementia, or another illness, instead of being a true side effect.

*“Sometimes you never know whether it’s even drug induced rather than through Parkinson’s in the first place.” GP5*

*“I think was Zyprexa that she was put on to, after a week she said it made her feel nausea but I’m not really sure that those symptoms were, were actually true.” RN1*

One of the GPs and a pharmacist felt that the side effects of psychotropic agents were often overstated and that they weren’t as bad as they were made out to be.

*“I do feel somewhat sceptical that it may have been a bit overdone, panic about falls and fractures and benzodiazepines.” GP4*

One of the reasons to account for this perceived lack of adverse effects associated with psychotropic medication is that they weren’t actually recognised as drug-related side effects by the health professionals. Indeed one pharmacist thought that many movement disorders caused by antipsychotics were not picked up by the nurses.

*“Probably the most common, if you are talking about antipsychotics and behavioural things, would be akathisia.(hyperkinetic movement disorder). That’s something that’s poorly, recognised by the nursing staff because it’s so similar to the underlying behaviour that they’re trying to treat.” P1*

#### **17.4 What are the barriers to the review of psychotropic medication?**

There were several barriers identified as to why psychotropic medications were not reviewed on a frequent basis or doses reduced. The superordinate theme that emerged to answer this particular research question was ‘if it ain’t broke, don’t fix it’. The subordinate themes were; ‘It’s only a small dose’; ‘Are there any Guidelines?’ and ‘GP-nurse communication’.

Apart from interviewing each participant, attitudes to reviewing and reducing psychotropic medication were investigated by presenting them with the vignette involving a hypothetical resident. One of the rationales behind the vignette was to observe how the

participants responded when they were offered the opportunity to review and taper off the psychotropic as professional guidelines recommend.

Most of the health professionals were well aware of the benefits of reviewing and reducing psychotropic medication. Several of the GPs and nurses could recall instances where this medication had been ceased and the resident's life had changed dramatically.

*"I had a patient that I took over who was on Mogadon and he was falling very frequently and we got him off Mogadon and his gait improved remarkably. ...and he was like a new man during the day."* GP1

*"We weaned her off that (clonazepam) and it's a miracle, she's a whole new vibrant lovely active person. It's just a miracle so that's one that will stick in my head for the rest of my life, I think."* RN7

Several of the health professionals referred to the disease progression over time that occurred in people with dementia, and said that at a certain stage, psychotropic medications were no longer required for most residents.

*"Cause they go through that challenging behaviour and then usually you've got a different person so why give them stuff if they don't need it."* RN4

#### **17.4.1 'If it aint broke, don't fix it'**

According to the accreditation standards, GPs are obliged to review and re-write resident's medication chart every three months. This regulatory requirement often prompted review as one of the GPs explained *"when I'm re-writing a drug chart I normally look at it and say is this necessary here, are we still getting benefit from these medications?"*(GP1) However, many of the nurses felt that medications were rarely changed or doses altered at the 3-month review.

*"From what I've seen of the drug charts here, it seems to be the same thing written up month after month after month after month. Very rarely does anything change, that's what I've noticed anyway, and I'll just say that that's pretty well right through. Through my twenty nine residents, very little gets changed"* RN9

The professional guidelines specify that if a resident with dementia is stabilised on an antipsychotic, a dose tapering attempt should be made every three months, with the view to eventual cessation.<sup>94</sup> Similarly, long-term benzodiazepine users should also be offered the



opportunity to reduce dose on a regular basis.<sup>95</sup> When asked how often psychotropic medications should be reviewed the health professionals varied in their response.

*“If they’re stable it (a review) would be annually.”* GP3

*“The ones that are on the olanzapine, (antipsychotic) probably I would feel quite comfortable with them being on that for the period of time.....all of them haven’t been on for that long, and it would probably be for twelve months but I’m sure that would be classed as not long.”* RN1

In the vignette, the health professionals were asked to consider a resident in whom risperidone, an antipsychotic, had been used for three months and the resident had stopped calling out. The majority of the health professionals; specifically, three of the GPs, seven of the nursing staff and two of the pharmacists opted to keep or recommend that the resident was kept on same dose of antipsychotic medication.

*“I think you’ll find that once people are stabilized they should stay what they’re on.”* GP3

*“I’d be saying well it’s been reported that this dose is working well for her and needs to be continued.”* EN10

The majority of nursing staff, and GPs were concerned about the ‘calling out’ returning if the medication regime was changed.

*“It’s a case of well we’ve fixed the problem so if we start playing with it we may end up with the problem again, so the GP leaves well alone.”* EN8

*“One of the troubles of this is that you reduce the dose and they get this behaviour and usually it’s the middle of the night when they’re having all the problems and then you have to, then it’s a problem to be managed for a day or two until everything settles back to normal.”* GP2

One of the GPs who did opt to reduce the dose of risperidone acknowledged that this course of action was likely to be challenged by the nursing staff.

*“I think it would be reasonable if she settled down completely depending on what dose you’ve had to use to consider reducing the dose of the risperidone. That’s where there’d probably be a bit of pressure from the Nursing Staff, you know, ‘that means all that calling out at night and it may start again’. ”* GP1

#### **17.4.5 ‘It’s only a small dose**

Another common justification for the extended duration of use of psychotropic medication was that this was acceptable practice because the dosages administered were usually quite low. Using ‘*Only a small dose*’ was perceived by many of the health professionals as not having too many repercussions for the residents.

*“We’ll discuss with the Doctor again how long she needs to be on it. I think it’s only a small dosage from what they say.” R1*

*“I would probably just continue on with the risperidone. If it’s a small dose, I would probably continue on with that but I don’t know if that’s the right thing to do” RN9*

Being on a small dose was also used to justify not reducing a medication by two of the GPs.

*“If she’s on maximum doses then I would think of reducing it. But if she’s actually, if she’s controlled on a small dose once a day I probably wouldn’t change it, I would probably leave it there.” GP5*

*“If you’re talking of quite low doses of medication, it probably doesn’t make an awful lot of difference as far as the resident goes. I can understand high doses of sort of. It’s certainly worthwhile considering could this patient cope with less- but if you’re talking dropping from 2mg down to 1mg. Is it really worthwhile to disadvantage everyone with the bad behaviour and the disruption to the ward?” GP2*

It should be noted that the maximum recommended dose of risperidone for older people with dementia is 2mg and this higher dose is associated with significantly more sedation, gait disturbance and a higher rate of movement disorders than the 1mg dose.<sup>119,546</sup> Thus a halving of the dose, as suggested in this case, would be likely to impact the resident.

#### **17.4.6 Are there any guidelines?**

Throughout the interviews with the health practitioners it became obvious that very few had adopted evidence-based practice regarding psychotropic use. None of the health practitioners said they referred to professional guidelines when they prescribed, dispensed, administered or reviewed psychotropic medication. In fact, the majority of GPs, nurses and pharmacists were unaware of their existence. One pharmacist and one GP referred to information regarding benzodiazepine use they had received from the National Prescribing Service several years ago, however these publications cannot be classified as professional guidelines. There are several

guidelines released by the Royal College of General Practitioners to aid medical management in RACFs and there is also a specific guideline from the College on benzodiazepines<sup>95,164</sup> Both mention the need for caution when prescribing psychotropic medication in older people and recommend regular reviews of treatment. Moreover, the RANZCP has recently released a practice guideline on the use of antipsychotics in dementia which specifically states *“It is important that the need for ongoing treatment is reviewed on a regular basis (such as three monthly) and, where appropriate, attempts are made to withdraw the medication.”*<sup>94</sup> As none of the health practitioners knew about these guidelines, most reported that they generally relied on their own personal experience with psychotropic medications to guide their use.

*“I don’t know if there are guidelines to those things, I don’t follow them.” GP3*

*“Usually it’s just clinical experience, background.” P1*

About half of the nursing staff said that they would check the ‘MIMs’, which is a listing of drug company monographs providing company information about doses and common side effects; however, this reference does not provide professionally-endorsed practice guidelines for medication use. Like all of the other health professionals, the nursing staff said they often relied on direct clinical experience to guide use.

*“If it’s a drug I don’t know I always look it up in the MIMS but that’s as far as I go, otherwise my only guidelines are observing the resident and seeing whether it’s got a positive or a negative.” RN4*

#### **17.4.7 GP-nurse communication**

One of the barriers cited for the infrequent review of medication was poor communication between the GPs and the nurses. Although none of the GPs mentioned that they had problems communicating with RACF staff, communication problems with GPs were reported by all five ENs and three of the RNs. Nonetheless, two of the RNs did claim to have good working relationships with the GPs.

*“I have a very good rapport with them all and they would always listen to me..if I ask for something, a visit or review they do attend. I can’t say that they would do the same for some of the junior staff.” RN7*

Most of the nursing staff recalled difficulty getting GPs to come in to review medication charts. Some of the nurses at certain facilities had lost faith in getting GPs to review medications.

*“As for us physically ringing them up and saying come and review, no probably it doesn’t happen. You have the problem where it’s hard enough to get them here when there’s an acute illness, let alone getting them to come in and review a drug chart or something.” EN8*

Several of the nurses felt that some of the GPs were dismissive of their suggestions or ignored their assessment of the resident’s behavioural problem.

*“A lot of GPs,...they think they know what they are doing basically, and won’t, yeah, take on board what you are saying” RN5*

*“Well I documented every time this lady had her paranoid episodes but I don’t know whether her G.P. actually read any of the things that I was writing.” EN5*

Nurses also reported that on occasions the GPs ignored the advice of external agencies as well as the nursing staff, preferring to exert control over the prescribing process, as this case below illustrates:

*“I’ve got a lady that’s 98 and she started to become a little bit confused and wander at night. So I got ‘Dementia Support’ to come in and she’s on Serepax 15mg at night and she’s also on Valium 2.5 mg twice daily when needed. So dementia support said to me she’s probably been on Serepax for 50 years, maybe you could gently say to the G.P. that it’s probably not helping her confusion. So I rang the G.P. and said “they’ve recommended that she not have the Serepax”, and she said “oh no, no, no, I want her to have the Serepax, I’ll cancel the Valium and we’ll put her onto Serepax, three times a day. And I said “do you mean you want me to give her Serepax 15mg morning, in the afternoon and 30mg in the night? She said “yes I do”. So I think she had that for about two days and oh God she was, absolutely, you can imagine what she was like.” RN4*

### **17.5 What are the roles of GPs, nursing staff, pharmacists and the resident’s family when psychotropic medications are initiated and reviewed?**

There were strong views expressed regarding who exactly was responsible when psychotropic medications were initiated and reviewed; however, there was often differences between what was supposed to happen and what actually happened in practice. The superordinate theme that emerged was that ‘nursing staff play the central role’ in regards to psychotropic medication initiation. However, it was unclear who played the main role when it came to psychotropic review. As the legal prescribers, GPs are obliged to play an important role when these medications were utilised, yet many were reluctant to take on this responsibility due to time and

financial constraints. To the contrary, the pharmacists and the resident's family had minimal involvement when psychotropic medication prescribing decisions were made. Thus the subordinate themes were 'GP involvement', 'relative non-involvement' and 'It's not what I do', the later theme representing the pharmacist's role.

#### **17.5.1 'Nursing staff play the central role'**

Most of the participants felt that nurses were the people who were in direct contact with the resident for *"twenty-four hours a day"* (GP5) and that consequently the nursing staff were ideally placed *"to pick up any changes in their situation."* (P4) There were several instances recalled where nurses had strongly influenced the decision to prescribe or withhold psychotropic medication.

*"For these two residents I was saying that they were getting difficult at teatime and bedtime. I spoke to one G.P. and she said, we might try a dose of risperidone and we tried it at 2 o'clock in the afternoon and that resident has settled totally so, when the other resident was being difficult too I suggested to his G.P. who said yes we'll try it - so both those residents have risperidone at 2 o'clock in the afternoon and both of them are good."* RN9.

*"She hadn't slept the previous night and so the nursing staff had decided to withhold her risperidone the next night in case that made her hyped up."* GP4

With regards to the review of psychotropic medication, a few of the more senior registered nurses were quite proactive.

*"I made the G.P. sit down and said let's look at her medications, and I'd been on about it, banging on about it for a long time, and can't we just try something else or try and wean her off and see what happens."* RN7

In contrast, several of the nurses were more cautious about overstepping the authority of the GP.

*"I wouldn't actually suggest a medication but I would say how about we change the medications and see what they come up with."* RN4

One of the GPs felt that the nursing staff should be given greater responsibility:

*"That's a problem in RACFs. If it's not written down then they can't give it...even though the nursing staff should be able to follow all these things themselves without the need for doctor's prescribing."* GP2

Although the GPs generally agreed that the nursing staff were responsible for behavioural management to a large degree, all of the GPs thought that RACFs were understaffed and several GPs referred to difficulty even locating the nursing staff when they visited:

*“You get to the Home and it’s often quite difficult to find staff. You’ll have to find a staff member if you want to get the drug chart out before you see the patient. And then if you want to discuss the patient afterwards, you’ll have to again look for a staff member.” GP4*

### **17.5.2 GP involvement**

The majority of nurses and pharmacists expressed the opinion that most of the GPs did not want to become involved in the management of challenging behaviour and insomnia in RACFs.

*“Sometimes I think that, their (the GPs) attitude is for you know, “you deal with it”, you know, if it’s nothing that’s going to cause any physical injury.” RN5*

One of the GPs explained why aged care was unattractive to GPs:

*“I think in terms of attracting doctors to do more RACF care, it’s addressing issues such as proper remuneration. You know there’s just no attractiveness for young doctors to leave their surgery and go and look after RACF patients.” GP1*

Importantly, there were several examples reported by the nursing staff where the non-involvement of GPs impacted upon the care of the residents.

*“There are several of them.(GPs) If I didn’t ring them up and say you haven’t seen your patients for three months and if they die, there could be an issue, they’d never see them.” RN4*

*“The GPs might only be there three days a week and so the other four days a week they don’t actually have a doctor other than ‘After Hours’, and they hardly ever come in when you ring them. So there’s a lot of time these people don’t actually have doctor backup.” EN8*

In spite of difficulties attending RACFs, the GPs were often resistant to suggestions from the nursing staff. It appeared that although they wanted minimal contact with RACFs and did not want to review medication charts, they were quite reluctant, at the same time, to lose control over the prescribing process. Several nurses cited examples where they felt they couldn’t express what they felt was best for the residents and their suggestions were overridden. The nursing staff often expressed frustration with this situation.

*“It’s just like a catch 22 situation where you have to do what the doctor wants done and yet you know in your own mind that it’s probably not to the advantage of the patient to be having medications that they’re probably not needing.” EN8*

*“Some GPs are quite resistant to any suggestions you can make.” RN9*

### **17.5.3 Relative non-involvement**

The GPs, nursing staff and pharmacists thought that there was marked variability in the degree of involvement family members wanted when it came to the medication management of the residents. Many felt that this reluctance to get involved was linked to the distress relatives felt about their relative having dementia.

*“I think with dementia a lot of them (relatives) don’t want to actually be involved, they’re a bit afraid of what’s happening to their parent. There are a few that like to know everything, they want to know what the medication is, what it does, or if we’re trying different strategies.” EN3*

*“Not too involved, ‘cause they (family members) can’t handle it .....Most families are quite compliant or quite happy to control whatever it takes to settle the behaviour down. A small amount of families are quite upset with any minor alteration of medication such as an anti-depressant or anti-psychotic and often refuse them.” GP3*

The relatives themselves also expressed varying interest in the medications of their relative.

*“I do want to know what she’s having because I don’t want them doping her up with all this stuff that she doesn’t really need.” R1*

*“I don’t have to be continually consulted about their medication because I really don’t know what each thing does or is for and as long they’re happy and content and looked after it really doesn’t and that doesn’t benefit for me to know everything like that.” R5*

All of the residents interviewed were legally responsible for the medical care of their relative. This means that their consent should be obtained before medications are initiated or altered. However, consent was rarely sought in practice. Relatives often mentioned that they found out about medication changes after they had been made rather than beforehand.

*“He (the GP) did change the blood pressure pills which I only noticed when I got the pharmacy bill and I asked him about that and he said why he’d done it. And I didn’t say well the next time*

*that you change his medicine can you tell me first but I thought that somebody could have done.” R3*

When the GPs were asked if they involved the family when changes to psychotropic medication were made they said it would depend on the degree of involvement relatives sought or the type of medication used. When one of the GPs was asked whether they would discuss medication use with a resident they answered:

*“Sedatives, I may or may not. I probably wouldn’t with a benzodiazepine, I probably should, and I certainly did with the anti-psychotics.” GP4*

More often however, it appeared that the residents were only informed after the decision had been made so true consent had not been sought or given.

*“Certainly we would let them know, when the family visited, that there had been a change in the medication but not, not beforehand no” RN5*

There also appeared to be some uncertainty over whose responsibility it was exactly to inform the relatives of medication changes. Some of the GPs said they would contact the relatives but two of the GPs thought that it was a nursing staff responsibility to inform relatives about medication issues.

*“Generally I wouldn’t contact them for a medication change but I would generally say let the nursing staff to contact the family about the change, but that probably doesn’t happen.” GP3*

*“They’re not always consulted beforehand about what medication, ‘cause that’s up to the GP to discuss that.” EN8*

The nurses and the GPs were generally not supportive of relatives being involved in decisions about medication management. There was one instance discussed where the GP had gone against the will of a relative and another where the nursing staff at the RACF had managed to ‘talk the relative into’ using psychotropic medication.

*“I knew there was resistance from the family. I just started a low dose SSRI and her son found out and went beserk and irate - and the comment was back how dare you start an SSRI and don’t you dare put her on an anti-psychotic.” GP3*



*"We always notify, sometimes there've been the odd occasion where I've had a refusal. I've had one quite recently and this lady was quite distressed and did really need a little dose and she's responded really well. But her family.... they just sort of said, no we just don't want her to have anything.... We did manage to, not talk them round but convince them that yes it was worth a try and made the promise that we would monitor carefully and keep them updated."* RN7

When one of the relatives questioned the nursing staff about antipsychotic medication she was informed who was 'in charge'.

*"Cause I made a comment once when he was being a bit disruptive, I said "has he had his haloperidol?" I was told (by a nurse) very briskly, 'I will decide if he has haloperidol'."* R2

Only two of the health professionals, a community pharmacist and a GP, referred to the legal requirement of consent when medical treatment is altered.

*"I think technically, although it doesn't really happen, you've got to have consent from the family."* P5

#### **17.5.5 "It's not what I do"**

One theme that emerged in this study was an uncertainty over whose role it was to review psychotropic medication. Accredited pharmacists have been providing medication review services to RACFs for over ten years. All of the GPs and the nurses interviewed were highly supportive of the service.

*"The other thing influencing the prescribing is the Pharmacy Reviews."* GP5

*"I find them (the medication reviews) yeah great to look at just to see what has been suggested and what you know. It's quite interesting to actually be on a shift when the G.P. comes back in after a sort of medication review has been done and you sit down and speak to them about what's been spoken about or thought about in the medication review."* EN6

Several of the nurses said that one method they used to address medication issues with GPs was to ask the pharmacist doing the medication reviews to discuss the issue with the GP.

*"If I can't resolve it (a medication query) with the GP, he (accredited pharmacist) will organise for that to be highlighted, yes and it has been successful."* RN7

When specifically asked if they recommended changes to psychotropic medication the three accredited pharmacists expressed some reservations. Two of the pharmacists said they did not usually address psychotropic prescribing issues. One of these pharmacists said she usually reminded the GP to review psychotropic medication in her report rather than suggesting any changes herself.

*"It's (sedative medication) not a specific target of what I do in terms of reviews." P1*

*"A recommendation that I have done to suggest that they review it (a psychotropic medication) once they've settled in." P4*

The pharmacists reported they would probably be more likely to recommend dose reductions of benzodiazepines rather than antipsychotics, and one of the GP's agreed with this stance.

*"They do often recommend decreasing benzos. But in terms of actual medications like anti-psychotics, now you bring it up, I can't actually remember any change recommendations to those medications." GP3*

It appeared the main reason for this reluctance to review psychotropic medications, particularly antipsychotic therapy was due, in part, to resistance encountered from the GPs and nurses.

*"The general answer I got from either the GPs or the nurses, or both was; "they need it". "can't do without that", or "tried to stop that before...didn't work." P1*

*"Like yesterday for instance, prompting a review of benzos use in the elderly and the nurses were involved in discussions with the doctors and 'gee the night staff are going to hate us for this', and so there's always that attitude that someone's going to have to deal with it if it goes wrong." P2*

In contrast to his view above, this particular pharmacist found there were a few facilities that did accept his recommendations without opposition.

*"A couple of weeks ago when I went to a home where whenever I prompted that (a reduction in benzodiazepine dose) the nursing staff said 'great, yeah, we'll give it a go and if any problems result then we'll treat it and return back to what they were or restart the agent'." P2*

All of the pharmacists said they often sought the nurse's opinion about medication-related issues that any of the residents might have. Likewise, nursing staff often would approach them with any issues.

*“If they’ve (the nursing staff) got concerns that they want fixing and then they tell us straight away as soon as we hit the home.... I mean it’s giving us good direction of the review that we should be doing because that is the current issue.” P2*

However, like with many aspects of RACF care, availability of the nurses was cited by the pharmacists as a barrier to their involvement in the review process.

*“Our main barrier (to do medication reviews) is, in fact, nursing staff, allocation, availability - for critical discussions regarding the residents. “ P1*

Yet, this interdisciplinary way of working was, in the opinion of one of the accredited pharmacists, the most effective way to improve a resident’s medication management.

*“How we use the nurses in a multi-disciplinary discussion is to say; “well you tell us the symptoms, the care implications, the issues with this particular resident”. The doctor can inform us about the medical history, the other issue such as the laboratory tests. We can bring to that what we know about the drugs and potential adverse effects, and different use of them.... and when we have a three way discussion, that’s usually our most effective way of improving a person’s medication management because each of us know different things.” P1*

## CHAPTER EIGHTEEN: DISCUSSION

### A QUALITATIVE STUDY OF PSYCHOTROPIC PRESCRIBING IN TASMANIAN RACFS:

This is the first known Australian study to engage in an in-depth exploration of RACF psychotropic medication use in-depth. Moreover, there are very few published studies in the scientific literature that have examined the controversial issue of psychotropic use in residential aged care using qualitative approaches. While one qualitative study was undertaken by the National Ageing Research Institute (NARI) in 2004, this study aimed to identify barriers to implementing 'restraint-free care' in RACFs with a focus on the use of physical restraint rather than the use of pharmacological or chemical restraint.<sup>507</sup>

As the data in the proceeding chapter highlights, the findings of this research reveal that the factors influencing the initiation and review of psychotropic medications are multifaceted and complex. Indeed, they describe many barriers to the review and dosage reduction of these agents. In particular, they highlight that the roles of health practitioners and relatives in the context of psychotropic medications being started or reviewed were contrary to that that might be expected under existing systems and legal frameworks.

The aim of this study was to answer three key research questions:

- Why are antipsychotics and benzodiazepines used extensively in RACFs?
- What are the barriers to the review of psychotropic medication?
- What are the roles of the health professionals and the resident's family when psychotropic medication are initiated and reviewed?

The findings when antipsychotic and benzodiazepine utilisation in RACFs were examined are discussed under the headings of the study questions.

#### **18.1 Why are antipsychotics and benzodiazepines used extensively in RACFs?**

'Comfort' of the resident was the dominant theme emerging from the research to justify why psychotropic medications were prescribed and used for extended periods. These medications were prescribed and use maintained to make the residents more comfortable. For most of the participants interviewed, if the resident was perceived to be 'comfortable' after taking a psychotropic medication then it was considered to be effective. On the other hand, the more clinically trained respondents, the GPs and accredited pharmacists, as well as a few of the nurses and relatives expressed doubts about the effectiveness of the medication to treat the actual presenting mental health condition. The latter professional opinion aligns with the clinical

trial data which consistently reports that antipsychotics are only modestly effective in treating BPSD, reducing agitation in about 20% more patients than placebo.<sup>251,254</sup> Likewise, benzodiazepines have been shown to lose effectiveness as hypnotics after 2-4 weeks, and as anxiolytics, after 4-6 weeks.<sup>133</sup>

One of the problems with perceiving psychotropic medication as providing ‘comfort’ is that this sets up the opposing view that if these medications aren’t prescribed then the staff must want the resident to be uncomfortable or distressed. This perception constructs the administration of psychotropic agents as ‘humane and caring’ despite evidence that they can cause significant adverse effects in this frail older population.<sup>112</sup> This perception also gives rise to the phenomenon of what is termed ‘anticipatory’ prescribing where these agents are prescribed for extended periods to ensure that the residents remain ‘comfortable’, in the absence of behavioural symptoms.<sup>62</sup>

Many of the participants interviewed felt that these medications improved the residents’ quality of life mainly because they felt personally that it wouldn’t be nice to be agitated or to have minimal sleep at night, whereas a lesser number felt that they these drugs did just the opposite; decreased the quality of life of the residents because it wouldn’t be nice to be ‘zonked out’. It was difficult to establish whether the different participant groups or participants from different RACF had the same opinions about the quality of life of residents. There was marked contrast between the individual views of all participants no matter whether they were relatives, health professionals, or which RACF they worked in. These opinions illustrate the very subjective nature of this debate, but also beg the question if there is any research evidence to support the proposition that psychotropic medication improves the quality of life of older people?

For any disease state and associated treatments, the impact on quality of life is a key consideration. It is often assumed that residents with BPSD have a poorer quality of life but there are few studies to support this assertion.<sup>547</sup> One study reported that approximately one third of residents with BPSD experience distress from these symptoms.<sup>548</sup> Distress, most clinicians would concur, would be likely to compromise quality of life.

A cross-sectional study, based in the U.K., involving 112 residents in care homes, attempted to evaluate the relationship between BPSD and quality of life measures using the ‘Dementia Care Mapping’(DCM) tool.<sup>549</sup> Although more than half of the residents had clinically significant BPSD, it was found there was no significant association between any of the quality of life parameters, including well-being, social withdrawal or participation in activities and the experience of BPSD.<sup>549</sup>

The researchers in this same U.K. study also considered the important question if antipsychotic medications improve the quality of life of residents with dementia? It was found

that the 46% of residents taking antipsychotic treatment spent significantly less time engaged in activities than residents not taking antipsychotics; in addition, the 'ill-being' score of the medicated residents was significantly higher than non-medicated residents. The authors of the study concluded that the antipsychotic agents were actually 'more detrimental to quality of life than the symptoms for which they were prescribed.'<sup>549</sup> Similarly, in the CATIE-AD study a separate analysis was performed to evaluate the impact of atypical antipsychotic treatment on measures of functional ability, quality of life and caregiving time needed.<sup>550</sup> These ratings were assessed at baseline and at week 12 of the study. On the activities of daily living scale, patients taking olanzapine showed significant worsening of functional ability compared to placebo at week 12; however, no significant differences were observed between patients treated with an antipsychotic and those treated with placebo at week 12 on functional, quality of life and caregiver scales.<sup>550</sup> Although research in this area is limited with more research needed, studies to date suggest that psychotropic medication may not actually improve the quality of life of older people with BPSD as much as is supposed.

Research has shown that the perceptions that health practitioners have about older people, particularly those with dementia influence the quality of care they receive.<sup>525</sup> Many of the health practitioners recounted very negative experiences with residents, which, perhaps would be expected because they were asked to recount experiences of challenging behaviour. None of them recalled positive aspects regarding a resident and several referred to the residents collectively; that is as 'they're very difficult' or those residents 'with the dementias', thus depersonalising the residents, rather than valuing each resident's 'personhood'. This underlying negative attitude about the residents displaying behavioural and psychological symptoms is also likely to influence the way medical staff perceive the resident's quality of life and thus affect decisions whether or not to prescribe and continue to use psychotropic medication for them.

What the present study has shown is that the personal opinions of the health practitioners regarding the comfort and quality of life of residents with mental health conditions is a key determinant on the use of psychotropic agents in RACFs. Health professionals and relatives with residents in RACFs need to engage in active discussion about whether psychotropic medications are the most effective solution to improving the comfort and quality of life of residents with mental health conditions. Training on dementia may help to improve the negative attitudes that many of the interviewees hold regarding these residents. Such training may also impact on the health practitioners' perception of the quality of life that many people in RACFs are getting and the impact that psychotropic medication has on this. Non-pharmacological strategies may be a more effective option to improve the 'quality of life' of many of these residents.

### **18.1.1 Lack of time for one-on-one**

The majority of health care staff interviewed demonstrated a wide knowledge and appreciation of non-pharmacological strategies to manage the behavioural and psychological symptoms of residents. The most effective of these strategies was thought to be ‘one-on-one’ activities. It is one of the ironies of this study that most of the nursing staff, although showing a strong appreciation of the benefits of ‘one-on-one’ activities, did not have the time to implement them. This finding concurs with a recent focus group study, conducted in a sample of 35 nurses in the U.S., where ‘time’ emerged as a key barrier to the use of non-pharmacological interventions.<sup>551</sup> Staff in this U.S. study, like in the present study, felt that there were “insufficient staff to do the needed ‘one-on-one’ interventions”.<sup>551</sup> Some of the participants in the present study felt that psychotropic medications were used when non-pharmacological strategies could be effectively applied. In this way, psychotropic medication was viewed as being a less staff-intensive way of managing the behaviour and poor sleep of residents.

One of the observations of an EN was that she wished she could spend more one-to-one time with residents to deliver non-pharmacological strategies but she felt her time was restricted because she was obliged to ‘do the medication round’. This nurse has a valid point. A recent study in Canada demonstrated that a medication round for 20 high care residents takes an average of 84 minutes.<sup>552</sup> Within a typical 7-hour day shift, which includes two medication rounds, medication administration would account for approximately one third of total nursing time. Obviously, with so much time required for this one task, the amount of time available for direct care of residents would be impacted.

In the present financial climate, markedly increased funding for nurse staffing is unlikely to occur. New ways to utilise ‘one-on-one’ strategies need to be considered. One of the findings in Kolanowski *et al*’s. U.S. study was that ‘non-pharmacological’ treatment appeared to be ‘owned’ exclusively by the nursing staff.<sup>551</sup> Similarly, in the present study, the non-pharmacological treatments to manage behaviour and sleep were considered to be the responsibility of the nursing staff by all participants interviewed. None of the relatives recalled instances where they were asked to be involved in these types of approaches even though most were present at the RACF for extended periods of time. GPs were also rarely consulted about non-drug approaches either, the majority admitting that they felt their input was only necessary when medications were needed. An interdisciplinary approach to the provision of non-pharmacological strategies, involving more members of the health-care team, but also involving relatives, may offer the potential to increase the amount of one-on-one time spent with residents and thus reduce the need for psychotropic medication.

### **18.1.2 Lack of knowledge regarding psychotropic medication**

Information that may impact the perception of whether or not a medication improves quality of life would be knowledge of clinical trial evidence around its use, its adverse effect profile and long term safety data; data which ultimately shapes practice guidelines for their use. Adequate knowledge of mental health in older people is also associated with improvements in quality of care and can assist health care staff to gain greater insight into the challenges faced by older people with mental health conditions such as dementia.<sup>523,553</sup> Adequate knowledge is also critical for the accurate assessment and treatment of the behavioural and psychological symptoms of these individuals.

Only one of the health practitioners who cared for, or provided health services for, residents in this sample of RACFs displayed adequate knowledge relating to psychotropic medication use. To start, few of the health practitioners in this study were aware of practice guidelines to guide antipsychotic and benzodiazepine use in older people. It also became apparent throughout the interviews that the underlying pharmacological knowledge relating to the use of these agents was poor, especially amongst the nursing staff and some of the pharmacists. Likewise, many of the nursing staff were not aware of significant side effects or long term safety consequences relating to the use of these agents, particularly antipsychotics. It would be difficult to monitor for adverse effects of medications, movement disorders for example, if you were unaware what they were.

Several of the GPs and pharmacists also expressed the opinion that the risks associated with many of these agents were exaggerated and this opinion would be likely to influence impact prescribing practice. Similarly, many of the health practitioners felt that as many of the psychotropic doses prescribed were quite small, this would minimize the side effects of the medication. What is interesting to note with this last observation is that, pharmacologically, if a medication dose is high enough to produce an effect, then it is certainly high enough to produce side effects as well.

The perception that the doses of psychotropic agents are low may also be misguided. In stage one of this thesis over a third of benzodiazepine doses prescribed were considered to exceed maximum geriatric doses and the 12% of antipsychotic users were also prescribed excessive doses. In the absence of any guidelines for use, the GPs may not be aware of recommended doses for psychotropic medications. For instance, in one of the interviews, the GPs considered 2mg of risperidone to be quite a low dose, when in fact this dose is the maximum recommended daily dose to treat BPSD in older people.<sup>119</sup>

In order to reduce the levels of psychotropic prescribing in the RACF setting education regarding these medications for all levels of health care staff and the relatives of people in RACFs is sorely needed. There is limited evidence on the level of psychopharmacological



knowledge of health professionals working at RACFs, especially in Australia. One U.S. study, conducted over 20 years ago, indicated that many of the nursing staff possessed poor psychotropic knowledge.<sup>522</sup> In the present study, the health practitioners associated with behavioural management in RACFs were simply not equipped with enough knowledge about psychotropic effectiveness or the adverse effects associated with use. Professional guidelines on the appropriate use, dosage and duration of use of these agents for RACFs need to be adopted as a matter of priority. These guidelines need not only a wide distribution strategy but they also need to be accompanied by active promotion. A systematic review of the literature to identify barriers to guideline adherence found that in over 76 studies, over half of respondents were not aware guidelines existed, and even when aware, they were not familiar with them.<sup>383</sup>

### **18.1.3 Pressure to prescribe and inadequate assessment**

The data illustrates that many of the GPs felt pressure from nurses to prescribe psychotropic medication for residents. This observation is similar to one made in a recently published U.S. study by Cohen-Mansfield and Jensen in which 110 G.Ps were questioned about their psychotropic prescribing.<sup>554</sup> Almost 70% of the GPs believed that nursing staff request medications too quickly. Despite belief in non-pharmacological therapy and an awareness of the issue of overuse of psychotropic medication in RACFs, 80% of the GPs prescribed a psychotropic medication in the last case where they were contacted about a behavioural issue in one of their RACF patients.<sup>554</sup>

Although one GP in the present study said he was able to resist the pressure exerted by nursing staff, one of the GPs candidly admitted he would usually prescribe the psychotropic medication the nurses requested when they phoned. It should be noted that making the decision not to prescribe would probably necessitate a visit to the RACF. However, none of the GPs interviewed in this study felt they had the time or were remunerated sufficiently to be able to visit RACFs as required. If GPs are unable to visit the resident, nursing staff and relatives may feel compelled to 'pressure' the GPs into prescribing medication, often by phone, because this may be the only viable option to manage problem behaviour at the time.

A few of the nursing staff referred to occasions where relatives had requested psychotropic medication for their family member. However, none of the GPs could recall occasions where this type of medication had been requested by a relative. In contrast, most of the GPs and nursing staff recalled instances where relatives had asked for medication to be ceased or had not supported its use. None of the relatives participated in medication related decisions. This lack of involvement may be because they hand over the responsibility for care over to the RACF when their relative moves there. Pressure from the residents themselves for

psychotropic medication was rarely mentioned and in the few instances where this was recalled, appeared to be related to requests for hypnotic benzodiazepines.

Most of the GPs, nurses and pharmacists felt residents should be properly assessed for potential medical contributors when a behavioural symptom or sleep disturbance presented. This is important because many behaviours and sleep issues may be related to acute medical conditions, including a UTI, pain and delirium.<sup>261</sup> In the recent Cohen-Mansfield and Jensen U.S. study, 45% of the 110 GPs interviewed reported a medical source for challenging behaviour in their last consultation where they were required to treat a resident for this indication.<sup>555</sup> Because GPs were often unable to attend the RACF physically, this assessment was often performed by nursing staff with inadequate training, and over the phone. There were several instances recalled during the interviews where nursing staff had suggested the prescription of an antipsychotic for a resident just because the same antipsychotic agent had been 'effective' in another resident, which is a blatant example of inadequate personalised medical assessment. It is obvious that the existing system where GPs clearly struggle to provide adequate medical support services to RACFs may be one of the reasons why psychotropic use is so widespread.

## **18.2 What are the barriers to the review of psychotropic medication?**

All practice guidelines, both national and international endorse the regular monitoring, review and dose tapering of psychotropic medications in older people, particularly when prescribed to manage BPSD, anxiety and sleep disturbance.<sup>96,164</sup> There is a general consensus that antipsychotics used to manage BPSD should be reviewed on a three monthly basis.<sup>94</sup> Likewise, prescriptions for benzodiazepines should be time-limited, with long-term users encouraged to reduce dosages on a regular basis.<sup>95</sup> In RACFs there is a regular requirement for GPs to review and re-write the resident medication charts every three months. Although this requirement aligns conveniently with the recommendation that psychotropic medications be reviewed in the same timeframe, nursing staff, pharmacists and most of the GP respondents in this study reported that, on the whole, psychotropic review and dose reduction did not happen very often.

Both government and researchers have stated that the main reason for extensive psychotropic medication use in RACFs is because regular medication review does not happen and few attempts are made to trial lower doses or implement non-pharmacological strategies.<sup>398,486</sup> In the first stage of this thesis, over 60% of psychotropic medications were left unaltered over a year-long period. Only one in five residents taking psychotropic medication had agents ceased or dosages reduced. By comparison, the number of antipsychotic or benzodiazepine agents initiated in the sample of RACFs was significantly lower. The high rate of psychotropic prescribing appears to be related to the extended periods that residents are

staying on these medications rather than the prescribing of new agents. This finding emphasises the importance of regular medication review as a means to decrease the rate of psychotropic medication use in this setting.

In the present study a general resistance to trialling dose reduction was observed for several reasons. Firstly, many of the health practitioners were unaware of the professional guidelines that specify when review should occur. Further, many of the nursing staff were concerned that the behavioural symptoms of the residents would return if medication was altered. Finally, many of the participants felt that the dosages given were so small that reducing them wouldn't make a good deal of difference. All these reasons are indications of the poor knowledge base of health professionals around the use of psychotropic agents and provide additional evidence for the need for educational interventions.

Another reason cited for the lack of review was related to poor communication between GPs and the nursing staff. Many of the nursing staff said it was difficult to get GPs into their RACF to review medication charts and several felt that the 3-month review was often an exercise in re-writing rather than an actual review of the medication. About half of the nursing staff thought that certain GPs were often dismissive of their suggestions. There were several instances recounted where nurses had suggested a change of agent and had been overruled without explanation or that GPs had repeatedly ignored their request to review the medication. For this reason many of the nurses were reluctant to challenge the GP's authority and administered psychotropic medications even though they were not supportive of doing so. There was a sense of frustration expressed that they were the ones expected to make the assessment, manage and monitor the resident yet the GP always had the final say after minimal involvement. These opinions echo those found in a recent Belgian RACF study where RNs were interviewed about the use of benzodiazepines in which they reported an 'unequal balance of power between the two professions' regarding prescribing decisions.<sup>516</sup>

Successful nurse-GP communication has been defined as 'the ability to transmit correct information in an open and timely manner'.<sup>556</sup> Other aspects of successful communication include mutual understanding, respect, satisfaction and conflict management.<sup>556</sup> In a Swedish study, conducted in a sample of 36 RACFs, nurses were asked to complete a survey assessing the quality of nurse-GP communication.<sup>557</sup> The subscale on 'openness' of nurse-GP communication yielded the lowest score. Again, like much of the research conducted in RACFs, there was a wide variation in mean communication scores between facilities.<sup>557</sup> In the present study, the majority of nurses referred to problems they encountered with GPs and cited incidents where poor communication had impacted on the care of residents with behavioural and psychological symptoms. Although inter-professional communication may be better in some facilities than others, the issues raised appeared relevant for all nurses interviewed. For a more

effective medication review process, strategies to improve collaboration and teamwork between GPs and nurses need to be researched and implemented into day to day practice.

### **18.3        What are the roles of the health professionals and the resident's family when psychotropic medication are initiated and reviewed?**

Unsurprisingly, the findings of this study revealed that nurses played the key role when psychotropic medication was initiated; however, it was unclear who played the main role when these medications were reviewed. GPs sought limited involvement in both the assessment and review process, often due to restraints on their time and inadequate reimbursement. As a result, GPs relied extensively on the nurses to assess, manage and monitor residents with behavioural and psychological problems. Another consequence of GPs limited access is that much of the prescribing is done '*by fax or by phone*'. Although all the GPs interviewed said they attended the RACFs regularly, the majority of nursing staff and relatives referred to occasions when GPs had taken an extraordinary long time to visit a resident. Many of the relatives also said they found it difficult to get a GP to take on the care of their relative. Most of the GPs also felt that there was inadequate time and funding for them to look after residents in RACFs.

Voyer and Martin in a discussion paper on geriatric mental health nursing care put the case forward that nurses in RACFs play an important role during clinical assessment, must have the skills to recognise when a resident is using psychotropic medication inappropriately and can choose and assist with the implementation of alternative non-drug management strategies.<sup>518</sup> Unfortunately, none of the nurses interviewed in this study appeared to possess the knowledge base, time or staffing support to be able to do any of these aforementioned tasks effectively. It is apparent that none of the GPs or pharmacists had adequate time and support to effectively perform these tasks either, so one way to improve psychotropic medication utilisation in RACFs might be to promote an interdisciplinary approach where the three health professions work together to review residents with behavioural and psychological symptoms. Evidence for the effectiveness of this approach was seen in a Swedish intervention study, involving 34 RACFs.<sup>558</sup> The intervention comprised of 12 monthly interdisciplinary team meetings, involving GPs, nurses and pharmacists, and resulted in a significant decrease in inappropriate psychotropic prescribing.<sup>558</sup>

#### **18.3.1    Role of the Pharmacist**

Pharmacist-led medication review services were funded by the Australian government in 1998.<sup>49</sup> These services were strongly recommended by the NSW Government as a method to address the high usage of psychotropic medication in RACFs.<sup>39</sup> However, the provision of

RMMRs appears to have a limited effect on psychotropic usage rates and the appropriateness of psychotropic prescribing in Tasmanian RACFs. All residents in the 40 RACFs audited in the first stage of thesis had at least one medication review. Many of the resident's medication regimens were reviewed several times over a period of years; yet, the rate of benzodiazepine use was three times that reported in Sydney and the quality of psychotropic prescribing was poor in terms of inappropriate use, lack of recorded diagnoses, high dosages and extended durations of use.

The accredited pharmacists in the present study expressed some reservation when it came to recommending changes to psychotropic medication. This reluctance to tackle inappropriate psychotropic prescribing may have been related to their lack of knowledge about these medications and guidance regarding review; nonetheless, all of the pharmacists said there was marked resistance from nursing staff and GPs when it came to implementing changes to these medications. Similarly, Moore and Haralambous, in their study which aimed to determine the barriers to reducing restraint in RACFs, reported that a pharmacist was not supported by staff either when she attempted to reduce psychotropic medication use.<sup>501</sup> Some of this reluctance may be due to the fact that pharmacists visit each RACF once or twice a year at best, so do not develop a rapport with the staff at each facility. To be an effective member of the interdisciplinary team, and to have recommendations for review acted upon, more frequent visits may be needed.

The accredited pharmacists in this study said they welcomed and usually sought nurse involvement when they conducted RMMRs. Likewise, the nursing staff also valued the medication reviews that the pharmacists conducted. Although this communication was valued by both parties, participation in discussions about medication was often limited due to time constraints and staff shortages. It should also be noted that both GPs and accredited pharmacists are reimbursed to perform RMMRs whereas the nursing staff, or their employer, the RACF, is not.

As this study demonstrated, nurses play the key role when psychotropic medications are started. Nurses are also in the ideal position to contribute when these medications are reviewed. If there was greater involvement from the nurses when decisions to cease or alter psychotropic use were made they would be able to give an accurate assessment of the resident's present behavioural and psychological symptoms, directly monitor the resident, but more importantly, they would be more committed to the change itself as they contributed when the decision was made. Dedicated time and resources should be allocated to involve nursing staff in this important role of reviewing psychotropic medication.

### **18.3.2 Relative involvement when it comes to prescribing decisions**

Legally, all decisions to initiate and alter medications require the consent of the resident. If that resident does not have the capacity to be involved then a relative or a carer is usually appointed to be that resident's 'enduring guardian'. The 'enduring guardian' is thus required to consent to any medical treatment on behalf of the resident.<sup>505</sup> The findings suggest that this consent was not obtained when medications were changed or started in the present study. Reports from respondents indicated that the relatives were often only informed about changes that were made to therapy retrospectively, and that sometimes they found out this information by accident when they received a bill for the medication from the community pharmacy.

This lack of consent from enduring guardians was also noted in a recent Sydney study where the files of 77 residents taking psychotropic medication and not having the capacity to give informed consent were audited.<sup>506</sup> Guardian regulations were adhered to in less than 10% of cases. The main reason put forward to explain this finding was that GPs were often not aware of guardianship legislation.<sup>506</sup> This reason may also account for the lack of consent sought from the Tasmanian guardians in the present study. However, it became apparent that many of the GPs and nurse respondents did not believe that residents should be involved decisions regarding psychotropic medication. The GPs and nurses felt that many relatives did not want to be involved in these sort of decisions so they did not attempt to seek their consent. Of major concern is the finding that when residents expressed the view that they did not want their relative to have a psychotropic medication, one GP prescribed it anyway and one RN worked very hard to change the relative's mind. These two cases illustrate that both health practitioners had difficulty accepting that a relative would choose a treatment option other than the one they recommended. It is obvious that training on the concept of shared decision-making and on the guardianship legislation is urgently required.

Many of the relatives interviewed expressed the opinion that they put their faith completely in the hands of the GPs and nursing staff when it came to making decisions about medication-related matters. The main reason for this was that they felt they did not know enough about medications to be able to participate in these types of discussions. It is a legal obligation to obtain the consent of 'enduring guardians' before medical treatment is instigated or altered. However, it appears that the main barrier for this to occur is that the relatives simply do not have enough information about these medications to be able to participate in these decisions. These findings suggest that more attention should be devoted to giving the family drug information to enable 'informed decisions' to be made about them. At the same time, health practitioners involved with medications at the RACF should be prepared that relatives may decide that they do not want their relative to take these treatments. Although the guardian's

preference for treatment should be established and accepted, this situation will be difficult to achieve.

#### **18.4 Strengths and limitations of this study**

This is one of the first qualitative studies to have explored the issues around psychotropic prescribing in RACFs in depth. Participants were very open and honest about the way they felt which resulted in very rich and informed data. However, there were several limitations in this study that should be acknowledged. Although the participants of a qualitative study are not meant to be a representative sample, the health practitioners and the relatives interviewed were selected by the administrators of the RACFs involved. They may, therefore, be an ‘ideal’ sample of participants, possibly introducing bias. For instance, the GP interviewees all visited the RACFs frequently, whereas most of the nursing staff interviewed reported this was not common. Similarly, all of the relatives interviewed visited their family member several times a week, meaning they were more engaged in their relatives care than the ‘average’ relative. This increased level of involvement may mean that the participant’s views may be more positive or different than less-involved health care workers and relatives.

It should also be noted that all five of the RACFs from which the participants were based were selected because they had high psychotropic prescribing rates. This was done because the main aim of the study was to answer the key research questions, which related to high rates of prescribing and a lack of review of psychotropic agents. It was decided that facilities with very low rates of prescribing psychotropic medication would have considerable difficulty answering some of the questions such as providing examples how these agents affected the residents. Therefore the views expressed and main themes relayed may not be the same as in RACFs with lower psychotropic rates of use. In future work, it would be valuable to compare the views of staff working within high prescribing RACFs with the views of staff working in RACFs where these agents are prescribed at lower rates than average.

Another limitation of this study is that it was limited in terms of participant numbers due to resource constraints. In a study conducted in the ‘grounded theory’ tradition research data is usually collected until ‘saturation’ is reached. In this study; however, a pre-determined number of representatives from various health professional groups associated with five RACFs and relatives were selected to participate. The study was conducted this way because it was intended as an initial scoping exercise to provide vital information needed to inform the major intervention project and not a comprehensive examination into the determinants of psychotropic prescribing in aged care. However, in spite of predetermined numbers of participants, it was felt that saturation was reached regarding the majority of themes in this study, as very few novel viewpoints were raised in the last few interviews. Nonetheless, when the interviews were

analysed, it was thought that additional information from GPs serving the RACFs would add to the depth of enquiry. To address this concern, 3 additional GPs were contacted at this time but they all declined to be interviewed. For this reason, the views of GPs may be somewhat under-represented in comparison to those of the nursing staff and relatives. Future qualitative studies in this topic should consider interviewing a larger sample of participants until saturation is met.

### **18.5 Conclusion**

This qualitative study aimed to increase understanding of three key research questions. Firstly, why are antipsychotic and benzodiazepine medications used so extensively in RACFs? It was found that these medications are often prescribed with the intention of providing a measure of 'comfort' for residents and to improve their quality of life. Although health practitioners displayed a good knowledge of non-pharmacological strategies they were often unable to adopt them due to time constraints and staff shortages. Another important reason why psychotropic agents were used so extensively was often due to the inadequate knowledge of GPs, nurses and pharmacists about them, their adverse effects, doses and duration of use. None of the health practitioners used professional guidelines to guide the use and review of psychotropic agents.

The second question aimed to establish the barriers to the review of psychotropic medication. As many of the health practitioners were unaware of professional guidelines for the review of psychotropic agents they reviewed medication less frequently than recommended. Many of the health practitioners felt that problem behaviours would return if medications doses were reduced. Many of them felt that dosages were quite conservative and that reducing them would not make any difference. Yet, one of the main barriers identified was the uncertainty over whose exact role it was to do the reviews. Another major issue that resulted in inadequate review practice was poor communication between nursing staff and GPs.

The final question was what are the roles of GPs, nursing staff, pharmacists and the resident's family when psychotropic medications are initiated and reviewed? The nursing staff played the central role when psychotropic medications were initiated in RACFs. However, there was uncertainty over whose exact role it was to review these medications. GPs did not seek active participation in either role due to time and financial constraints. Pharmacists, although funded to perform medication reviews in RACFs, were reluctant to suggest review of many psychotropic agents partly because of resistance from GPs and nursing staff to reducing them. Relatives were not involved in decisions to initiate or alter psychotropic medication despite the legal obligation to do so.



**PART FOUR: ROLES FOR PHARMACISTS TO IMPROVE THE QUALITY  
USE OF PSYCHOTROPIC MEDICINES IN RACFS**

**An intervention trial**

## CHAPTER NINETEEN: INTRODUCTION

### INTERVENTIONS TO IMPROVE PSYCHOTROPIC USE IN RACFS

#### **19.1 Intervention framework**

The UK Medical Research Council has proposed a framework for the development and evaluation of complex interventions such as interventions designed to enhance the uptake of research findings.<sup>386</sup> This framework recognises the need to establish the theoretical basis for an intervention, define its components, undertake exploratory studies to elect strategies and refine interventions; and finally, conduct a definitive evaluative study, preferably a RCT.<sup>386</sup> The ‘RedUse’ project strove to follow the UK medical research Council’s framework.

To start, the theoretical framework selected for the intervention project combined a number of psychological and marketing theories, including persuasion communication, social cognition theory, and the transtheoretical and the PRECEDE-PROCEED models. The persuasive communication and social cognitive theories, and the transtheoretical model identify the need to encourage involvement and maximise social cognitive processing. They also highlight the need for continued repeated provision of information and opportunities for individuals to practice their new behaviour. Further, they suggest messages must be tailored and targeted to pre-identified groups. For this reason the ‘RedUse’ intervention aimed to deliver key messages to all health professionals involved with medication use in RACFs, with different distribution methods used for each the target health professional groups. Key messages of the project were delivered on numerous occasions using a variety of media. For example, the pharmacists undertook a 1.5 day training package on the intervention and regular follow-up phone calls; whereas nurses were given a series of two one-hour lectures, clear printed guidelines, newsletters and dedicated sedative review forms. Interdisciplinary communication regarding psychotropic prescribing was encouraged and discussion promoted throughout educational sessions with the specific aim of enhancing cognitive processing.

Another theoretical model underpinning the ‘RedUse’ intervention project was the PRECEDE-PROCEED model which identifies the need for understanding barriers and enablers for change before developing the intervention. For this reason, significant attention was directed to pre-intervention research where the main problem areas of RACF psychotropic prescribing were investigated and the determinants of psychotropic use in this setting sought.

Stage two of this thesis involved a cross-sectional retrospective study of a large sample of Tasmanian RACFs which aimed to establish the prevalence, review practice and quality of psychotropic prescribing. About two thirds of residents in this 2006 sample were taking at least one psychotropic medication, with a third taking two agents. The use of benzodiazepines was

three times the rate found in comparative studies in N.S.W and in New Zealand.<sup>38,420</sup> Over a third of residents were taking higher than recommended benzodiazepine doses for older people and 12% were taking antipsychotic doses above current recommended geriatric doses. Importantly, only one in five residents taking these medications had their dose reduced or ceased over a year of data collection, contrary to current good practice professional guidance.

Stage three of this research involved a qualitative study in which key participants when psychotropic medications are prescribed, administered and reviewed were interviewed, as well as the relatives legally responsible for their medical treatment. Antipsychotics and benzodiazepines were often prescribed in the belief that they would make residents more comfortable, thus improving their quality of life. Knowledge about these medications was generally poor and none of the health professionals referred to professional guidelines, leading to uncertainty about adverse effects, dose and duration of use. As GP access to RACFs was often limited, assessment of behavioural symptoms was often performed by nursing staff, with prescriptions routinely arranged 'by phone or by fax'. As a result, nurses played the central role when it came to initiating psychotropic medication; however, it was unclear whose responsibility it was to monitor and review this treatment. Pharmacists, although funded to perform regular medication reviews, were hesitant to review antipsychotic and benzodiazepine agents, principally due to resistance to suggestions to reduce use; and, finally, relatives were not sufficiently informed to be able to participate in decisions regarding their use.

The main aim of these two pre-intervention stages of this research and the initial literature review in stage one was to inform the fourth, and final, stage of this thesis; the 'RedUSE' intervention project which focused on promoting the review and quality use of psychotropic medication. The main objective of 'RedUSE' was not only to 'reduce' antipsychotic and benzodiazepine prevalence of use and improve the quality of prescribing but also to increase the rate of review and dose reduction attempts of these agents. Data from the initial stages of this research (Part two and Part three) informed the intervention project as follows:

- Firstly, due to the comparatively high use of benzodiazepines in Tasmanian RACFs, the main focus of 'RedUSE' would be on reducing benzodiazepine use, although the promotion of appropriate antipsychotic use would be an essential component as these agents appeared to be used interchangeably in many facilities.
- Second, although ideally, all health care practitioners would be involved in 'RedUSE', educating the RACF nursing staff, in particular, about risks and benefits of psychotropic medication in older people was considered a key objective due to the significant influence they exert on psychotropic use.
- Third, as psychotropic utilisation appeared to be influenced largely by personal opinion rather than on evidence-based medicine, a local set of guidelines on appropriate

antipsychotic and benzodiazepine use was urgently required and active promotion of these guidelines delivered alongside an education program explaining their use.

- Fourth, as one of the main determinants associated with psychotropic use appeared to be a desire to improve the ‘comfort’ and ‘quality of life’ of residents in RACFs, the educational sessions for RACF were structured so that open discussion was encouraged amongst the nursing staff about the benefits/drawbacks of psychotropic medication on a resident’s quality of life.
- Fifth, owing to their present lack of involvement contrary to legal requirements, relatives would also be informed about psychotropic medication, especially benzodiazepine use.
- Finally, as present data indicated a lack of pharmacist involvement in ensuring quality use of psychotropic medication, one of the main objectives in ‘RedUse’ was to assign the coordinating and educational role of ‘reducing’ antipsychotic and benzodiazepine use to pharmacists contracted to provide QUM services to RACFs.

In order to design an effective intervention aimed at reducing antipsychotic and benzodiazepine use in this setting not only was it important to have a theoretical framework, pre-intervention research to examine the barriers and enablers to the intervention, but it was also vital to learn from other interventions to reduce inappropriate psychotropic medication use published in the research literature.

## **19.2 Interventions to reduce inappropriate RACF psychotropic medication use**

Prescribing in RACFs has been recognised as being problematic for the past three decades.<sup>559</sup> Various approaches have been used in attempts to improve psychotropic prescribing practice in particular, including regulation, safety warnings, subsidy changes, educational programs, case-conferencing, computerised decision-support systems, clinical pharmacist medication reviews, audit and feedback and combinations of these approaches.

### **19.2.1 Regulation**

The first and only country to directly legislate to promote the appropriate use of psychotropic medication in RACFs was the U.S, with the national implementation of OBRA-87 in 1990.<sup>408</sup> Although initially focused on reducing antipsychotic use, these regulations have been modified over time to include standards for benzodiazepines, allowable geriatric doses, and regular dose tapering attempts.<sup>560</sup> If a U.S. RACF is deemed not to be attaining the required standard of care, a number of sanctions can be applied, ranging from in-service training to closure of the facility.<sup>561</sup>

So how successful was the OBRA-87 legislation in reducing antipsychotic and benzodiazepine use and improving the quality of psychotropic prescribing? Findings have been mixed, with the initial positive effect of the legislation on antipsychotic prescribing declining over time. When Rovner *et al.* assessed psychotropic use in a sample of 17 RACFs three months before and three months after OBRA-87 they reported a 36% reduction in antipsychotic use but there was no impact on benzodiazepine use.<sup>410</sup> Likewise, Garrard *et al.* performed a large cohort study of all RACFs in Minnesota three years before, and one year after, OBRA-87 implementation. Garrard *et al.* observed that although antipsychotic rates dropped by a third over the 4-year study period, the legislation had no impact on either anxiolytic or antidepressant use.<sup>562</sup> Borson and Doane examined psychotropic prescribing patterns in 39 U.S. RACFs between 1989 and 1992, reporting a decrease in both antipsychotic and hypnotic use; however, there was an accompanying increase in anxiolytic use and no change in the use of PIM anticholinergic antidepressants.<sup>560</sup>

In 1992, the U.S. government, recognising that the focus of inappropriate use was on antipsychotic medications, incorporated specific guidelines into OBRA-87 designed to reduce the unnecessary use of benzodiazepines as well. To assess the impact of this legislative change, Svarstad and Mount measured benzodiazepine use in 16 Wisconsin RACFs before 1990, and then again in 1993-1994.<sup>412</sup> It was found that the revised federal guidelines had a small, but non-significant, effect on the overall rate of benzodiazepine use (26.4% to 22.8%) and upon chronic benzodiazepine use, which declined, albeit non-significantly (9.2% to 7.9%).<sup>412</sup> The same authors examined the variation between the different RACFs in their response to the OBRA-87 regulation in relation to antipsychotic use.<sup>563</sup> The use of antipsychotic agents varied dramatically across RACFs, from a 85% reduction to a 19% increase, with greater reductions in use found in those facilities having a 'resident-centred' culture emphasising 'restraint-free' care and a collaborative inter-professional approach.<sup>563</sup>

In 1999, the Beers criteria for inappropriate medication use were incorporated into the government interpretive guidelines for surveyors of RACFs which is based on OBRA-87 regulations.<sup>561</sup> Judging the appropriateness of medication use is now reliant on extensive data collection, with all psychotropic medication use for residents needing to be justified and documented. In addition, monthly medication reviews by consultant pharmacists are now mandated, including an evaluation of the appropriateness of, and response to, each resident's drug therapy.<sup>561</sup> The pharmacist is obliged to report any irregularities to the attending GP and director of nursing. Two studies were performed to evaluate the impact of these revised OBRA-87 regulations on psychotropic use in RACFs. Lapane *et al.* assessed prescribing in a large sample of 1 142 RACFs in 1997, and again in 2000, but actually found an increase in benzodiazepine use from 17.9% to 19.8% over the three year time period.<sup>564</sup> Briesacher *et al.*

adopted a different approach to assess psychotropic prevalence by comparing a nationally representative sample of 8 million RACF residents from 1997 to 2000.<sup>565</sup> They found that although there was a small and significant reduction in PIM use, there was no difference in PIM use between RACFs with mandatory medication reviews and those without such services.<sup>565</sup> Both studies concluded that the effectiveness of a consultant pharmacist's medication review on improving the prescribing appropriateness appeared to be limited.<sup>564,565</sup>

There is only one known study aimed to evaluate the effect of the OBRA-87 regulation on resident clinical outcomes. Specifically, Hughes *et al.* aimed to determine if the reduction of psychotropic medication brought about through OBRA-87 legislation impacted the rate of falls found in RACFs. They did this by performing a retrospective cross-sectional study in which falls rates in RACFs in 5 states of the U.S. were compared to RACF rates found in five other countries: Denmark, Japan, Iceland, Italy and Sweden. Though psychotropic drug prevalence rates were at least twice as high in Denmark, Iceland and Italy, residents in these countries were significantly less likely to fall than residents in the U.S.<sup>566</sup> The researchers in this study concluded that although OBRA had decreased psychotropic prescribing rates, it was unclear if this reduction translated into better outcomes for the residents.<sup>566</sup>

Recent research has revealed that since the early 2000s, the rate of antipsychotic use has returned to pre-OBRA-87 levels, with several studies indicating that over a quarter of all U.S. RACF residents are now taking these medications, especially the newer atypical agents.<sup>91,413,414</sup> These findings provide evidence that a regulatory approach may not be the most effective when it comes to promoting the appropriate use of psychotropic medication, especially in the long-term. There have been criticisms of the U.S. regulatory system, with some advocates disputing that the regulation does little to improve the overall quality of psychotropic prescribing, and arguing that some residents may have missed out on necessary medications in a facility's quest to pass surveyor inspections. Furthermore, introducing legislation to countries like the U.K. or Australia may be '*anathema to many doctors who would consider it a challenge to clinical freedom*'.<sup>498</sup>

### **19.2.2 Safety warnings**

Several countries, including the U.S., Canada and the U.K., have released professional safety warnings regarding the use of antipsychotics in older people with dementia and associated risk of cerebrovascular events and mortality.<sup>268,567,568</sup> To date, there have been no safety warnings released in Australia. An important question to ask is if these safety warnings have significantly affected practice? Several recent studies have attempted to answer this question.

The first country to issue a government safety warning about antipsychotic use in people with dementia was the U.K., when the Committee on Safety of Medicines (CSM) released

advice that risperidone and olanzapine were associated with a threefold risk of stroke and a rise in all-cause mortality.<sup>517</sup> Shortly after this warning a working group, including members from the Faculty for the Psychiatry of Old Age, the Royal College of GPs, the British Geriatrics Society and the Alzheimer's Society, produced 'good practice' recommendations in light of the CSM warning.<sup>569</sup> A retrospective study evaluated the effect of the CSM warning and subsequent working group recommendations on 96 older patients prescribed antipsychotics by their GPs ten weeks after the CSM warning, and again 6 months later.<sup>570</sup> By six months after the CSM warning, 34 (65%) out of 52 patients with dementia had been withdrawn from medication. In time, two of these patients had to be re-started on the medication.<sup>570</sup>

A group of researchers from Canada also evaluated the effect of the HealthCanada safety warning by analysing prescription claims data from 2000 to 2007 (their safety warning letter was circulated in June, 2005).<sup>571</sup> Although the warning was associated with a small decrease in the predicted growth in the use of atypical antipsychotic drugs, the overall prescription rate of antipsychotic drugs increased by 20% from 2002 to 2007. Interestingly, the use of olanzapine and risperidone declined slightly but the use of quetiapine increased markedly, despite the fact that the safety warning was for all types of atypical antipsychotic drugs.<sup>571</sup>

In the U.S., two Federal Drug Administration (FDA) Black Box advisory warnings regarding antipsychotic use in older people have been issued; the first, in 2005 for atypical antipsychotics, warned that these medications were associated with increased mortality. The warning was re-issued in 2008 when it was extended to include typical antipsychotic medications.<sup>572,573</sup> In a time series analysis conducted from January 2003 to December 2008, atypical antipsychotic use in people with dementia increased at an annual rate of 16% from 2003 to 2005.<sup>574</sup> However, in the year following the FDA advisory warning, atypical antipsychotic use fell 19% among patients with dementia. By 2008, use had fallen even further.<sup>574</sup> Similar findings were reported in another time-series analysis study assessing national U.S. Veterans Affairs data across three periods: No warning (1999-2003), early warning (2003-2005), and black box warning (2005-2007).<sup>575</sup> In 1999, 18% of veterans with dementia were using antipsychotics. After the two FDA black box warnings, this figure had declined to 13%. Like in the Canadian study, risperidone and olanzapine use decreased while quetiapine use increased over this period.<sup>575</sup> In spite of these two studies showing evidence of a decline in use, one recently published U.S. RACF nationwide study indicated that 28% of residents received at least one antipsychotic during 2006.<sup>458</sup> And in 2008, antipsychotic drugs became the top-selling drug class in the U.S., edging out lipid regulators and proton pump inhibitors.<sup>576,577</sup>

In contrast to the latter prescribing data studies, when a web-based survey on the new FDA guidance was completed by 65 geriatric practitioners, less than half of the respondents

reported that the FDA warnings had changed the way they managed BPSD. The most commonly cited barriers for not taking into consideration the FDA warnings were: no alternative options, lack of guidance and lack of evidence of the benefits of changing practice.<sup>578</sup> There have been no known recent safety warnings released relating to benzodiazepine use; however, some administrative initiatives have impacted prescribing of these agents. In 2006, due to an administrative change in funding arrangements, RACF residents in one U.S. state were not subsidized for benzodiazepine medication at all. This change in funding resulted in a significant immediate decrease in RACF benzodiazepine use from 27% to 17% in this one state, whereas benzodiazepine use remained unchanged in those states with partial and full funding.<sup>579</sup> Substitution of benzodiazepines by other psychotropic agents became evident as the use of Z-drugs and other anxiolytic agents increased significantly, though not to the same extent as the overall benzodiazepine decrease.<sup>579</sup>

### **19.2.3 Educational initiatives**

Kane and Garrard, two American researchers, have argued that '*regulation is not the best way to control psychotropic prescribing choices*' and advocated the option of provider education through targeted, personalised approaches to GPs known as 'academic detailing'.<sup>580</sup> There have been a number of educational intervention trials aimed to reduce psychotropic use in RACFs; the major ones are summarised in Table 53. It is interesting to note that none of the educational interventions that were directly focused on educating GPs have been successful in reducing psychotropic rates. For instance, Ray *et al.* evaluated the impact of academic detailing to GPs identified as frequent prescribers of antipsychotic medication. Although well received by the GPs, the intervention did not result in a reduction of antipsychotic medication.<sup>581</sup> Similarly, in an Australian RCT in 20 RACFs and 10 hostels, Crotty *et al.* relied principally on a series of academic detailing sessions to GPs on psychotropic medication use, although one nurse in each RACF was also given 8 hours of training and a pharmacist spoke to nursing staff at each RACF/Hostel collectively about reducing psychotropic medication. Like the previous study, this intervention did not result in any reduction in RACF psychotropic rates.<sup>396</sup> In another Canadian study in 24 RACFs, GPs were invited to participate in 30 minute academic detailing sessions, with nurses and pharmacists offered short educational sessions. Again, no impact was reported on psychotropic prescribing rates.<sup>424</sup> In the last study, the researchers reported difficulty getting GPs to participate; however, this was not listed as a limitation in the first two trials. This lack of effect of academic detailing to GPs may be another indication of the limited influence that this professional group exert on psychotropic prescribing in RACFs. Interventions aimed at nursing staff may be a more effective method of impacting psychotropic rates and quality of use.



The most effective educational interventions listed in Table 53 have involved educating nursing staff about non-pharmacological strategies to manage BPSD.<sup>209,582-584</sup> Avorn *et al.* delivered a successful intervention program which involved a clinical pharmacist presenting a comprehensive teaching program to RACF staff about the appropriate use of benzodiazepines and antipsychotics.<sup>585</sup> In this particular intervention, 4 training sessions were delivered over a 5 month period per intervention facility and clinical information about psychotropic medication was also disseminated in three mailings to all GPs serving the intervention RACFs.<sup>585</sup> Direct one-to-one resident care, alternatives to psychoactive medication and recognition of adverse drug reactions were emphasised in the training sessions. This intervention resulted in a significant decrease in antipsychotic use and a reduction in long-acting benzodiazepine use.<sup>585</sup>

An intervention based in five Norwegian RACFs, focused solely on promoting appropriate hypnotic benzodiazepine use. Pharmacists held regular educational sessions with GPs and nurses to discuss hypnotic medications, and prescribing audit data was sent to GPs, nurses and administrators at the participant RACFs. This intervention did not significantly reduce the use of benzodiazepines in the participant RACFs over a five year period.<sup>586</sup> Instead, when the hypnotic prevalence rates were compared to rates from two control facilities at the end of the trial, the rates of hypnotic use in the intervention facilities were significantly lower. Without knowing the baseline rates of use in these control RACFs, however, it is not possible to conclude that this intervention prevented an increase in benzodiazepine prevalence.<sup>586</sup>

Another educational approach that was shown to be effective in reducing benzodiazepine use in RACFs involved educating the residents themselves. When Gilbert *et al.* conducted a benzodiazepine withdrawal trial in a South Australian RACF, over half of residents in the 60-bed facility were encouraged to reduce or cease use in an intervention involving education and relaxation training for patients, and education of GPs and nursing staff.<sup>475</sup> The proportion of residents taking benzodiazepines declined significantly (from 70% to 35%), and the reduction was maintained over the subsequent three months.<sup>475</sup>

The main lessons learnt from these intervention studies is that educational interventions offer the potential to reduce psychotropic use in RACFs. However to be successful they have to be directed primarily at nursing staff, involve the promotion of non-pharmacological strategies and include several sessions backed up by written educational materials. It is important to note that the majority of successful educational interventions in Table 53 were delivered by pharmacists.

One aspect of educational interventions that is frequently cited is that their impact is often not sustained without continued intervention.<sup>561,587</sup> For this reason, it is important to conduct follow-up studies of these interventions so that the durability of the training program can be assessed and the optimum interval between training sessions established.<sup>587</sup> Hughes *et al.* have

also argued that educational interventions need to be incorporated into everyday practice, and that one way to achieve this is to increase the involvement of pharmacists on a more proactive rather than retrospective basis.<sup>561</sup>

#### **19.2.4 Audit and feedback**

Audit and feedback strategies have also been utilised to improve psychotropic prescribing in RACFs, though only a few published trials have assessed its impact, with most of these trials involving benzodiazepines. In one U.S. study involving 10 RACFs, a pharmacist audited benzodiazepine use and presented feedback to GPs and nurses as well as sleep promoting guidelines. The intervention resulted in a drop of regular benzodiazepine use from 4.5% to 1.6%, with a small resultant increase in the number of 'prn' benzodiazepine prescriptions.<sup>588</sup> In one teaching hospital, an audit of benzodiazepine prescribing was conducted throughout the whole hospital and results were fed back to doctors, nurses and allied health practitioners. Although a decrease in benzodiazepine prescribing was not recorded, a significant increase in appropriate prescribing of benzodiazepines was recorded at 8 weeks (22%) and six months (30%) after the intervention.<sup>589</sup> The Australian Department of Veterans' Affairs through the Veterans' Medicines Advice and Therapeutics Education Service, or MATES, has also successfully utilised an audit and feedback program to reduce benzodiazepine prescribing.<sup>590,591</sup> In this specific program, GPs were sent an individualised list of their veteran patients receiving benzodiazepines, along with an information brochure on how to review and reduce them.<sup>590</sup> The audit and feedback program succeeded in reducing long-acting benzodiazepine prescribing in 35% of veterans.<sup>591</sup>

One recent U.K. study examined the impact of an audit in a single GP practice on antipsychotic use in their RACF patients.<sup>592</sup> Out of 81 residents, 27% were taking antipsychotic medications. Less than half of these residents had a recorded diagnosis and 36% had not been reviewed by a GP or psychiatrist in six months. These audit results were presented at a practice meeting and a review checklist implemented as a result. Six months later, when the residents were re-audited, the antipsychotic prevalence rate had dropped to 19% and all residents had a recorded diagnosis and a current review.<sup>592</sup> Audit and feedback programs are not always an effective means to promote appropriate psychotropic use. An example of an unsuccessful strategy can be witnessed in a Canadian RCT which evaluated the effect of audit and feedback on GP benzodiazepine prescribing for older patients.<sup>593</sup> GPs who were high prescribers of benzodiazepines were invited to participate, with 364 GPs agreeing. A total of 168 GPs in the intervention group were sent audits of their benzodiazepine prescribing every 2 months, as well as educational bulletins promoting good practice. After six months, the authors reported that the intervention did not significantly impact either the rates, or the quality of benzodiazepine use.<sup>593</sup>

**Table 53: Summary of studies that have employed educational initiatives to reduce psychotropic prescribing in the RACF setting**

Reference	Setting	Trial design	Design and components of the intervention	Outcomes
<b>Ray et al. 1987</b> <sup>581</sup>	Tennessee, U.S.	Controlled Trial (CT)	GPs given information about risks of antipsychotics and non-drug strategies promoted	No change in antipsychotic prescribing
<b>Avorn et al. 1992</b> <sup>585</sup>	12 RACFs Massachusetts, U.S.	Randomised Controlled Trial (RCT)	Pharmacist delivered an educational outreach program for GPs and nursing staff	More antipsychotics and benzodiazepines ceased in intervention group. Improvement in cognitive function in residents in intervention group
<b>Ray et al. 1993</b> <sup>583</sup>	4 RACFs Tennessee, U.S.	CT	GPs, nurses and admin staff received information about behavioural techniques to manage BPSD. Gradual dose reduction encouraged.	Significant decrease in days of antipsychotic use in intervention group. Frequency of behavioural problems unchanged
<b>Meador et al. 1997</b> <sup>584</sup>	12 RACFs Massachusetts, U.S.	RCT	GPs given education by psychogeriatrician. Nurses provided education on non-drug strategies for staff. Guidelines provided.	33% of residents ceased antipsychotics. Use of antipsychotics decreased from 25 days/100 to 20 days/100
<b>Eide and Schjott, 2001</b> <sup>586</sup>	7 RACFs, Norway	CT	Pharmacist provided verbal and written information about appropriate use of hypnotics to nursing staff	Significantly lower proportion of residents in intervention group used hypnotics (24% vs. 44%), Significantly lower use of multiple benzodiazepines in intervent. group (4% vs. 10%)
<b>Crotty et al. 2004</b> <sup>396</sup>	20 RACFs, 10 Hostels, Australia	RCT	Pharmacist delivered educational outreach program for GPs, nurses and admin staff	No change in psychotropic prescribing. Rate of 'prn' use increased in intervention group
<b>Fossey et al. 2005</b> <sup>209</sup>	12 RACFs U.K.	RCT	Training and support provided to nursing staff. Training involved non-drug interventions	Lower antipsychotic use in intervention homes (23% vs. 42%) Level of agitation between groups not significant
<b>Hagen et al. 2005</b> <sup>424</sup>	24 RACFs Canada	CT	Academic detailing by pharmacist for GPs, education sessions on psychotropic medication for nursing staff, pharmacists and relatives	No change in psychotropic prescribing rates
<b>Monette et al. 2008</b> <sup>582</sup>	1 large RACF, Canada	Longitudinal pilot study	Educational interdisciplinary sessions on non-pharmacological management of BPSD	50% of residents discontinued antipsychotics and 14% reduced dosages. Frequency of BPSD decreased significantly

In a recent Australian study, information about benzodiazepine use and ‘good practice’ was sent to GPs, RACF nurses and pharmacists in two areas over a 6-month period.<sup>594</sup> Although the study attracted large participation rates by health professionals, there was no significant effect on rates of RACF benzodiazepine use.<sup>594</sup>

Part of the reason for this lack of impact may have been related to the way the feedback was delivered. It appears that the most successful audit and feedback strategies give feedback orally, either in a meeting or an individual consultation, instead of just mailing.<sup>465</sup> A Cochrane review on audit and feedback concluded that interactive educational meetings incorporating feedback were more effective at changing practice than posted audits and educational materials on their own, and that multifaceted interventions incorporating education and feedback strategies offer the greatest chance of success.<sup>595</sup>

### **19.2.5 Medication review**

Three published studies have investigated the impact of medication reviews on prescribing in RACFs, two from the U.K. and one from Australia.<sup>42,596,597</sup> In addition, two unpublished Australian reports also evaluated the effect of pharmacist-led medication review services in low-care hostel settings.<sup>459,598</sup>

Furniss *et al.* examined the impact of pharmacist-led medication reviews over an 8 month period in a RCT conducted in 14 RACFs in Manchester, England.<sup>542</sup> Outcomes on medication use and clinical measures were assessed at baseline and at 8 months. At endpoint, there was a reduction in the number of all medications used in the intervention group, but not in the control group, although this difference was not statistically significant. Likewise, there were no significant differences found in MMSE scores, falls or mortality. The acceptance rate for recommendations among GPs was very high at 92%. Unfortunately, this trial did not report the impact of the intervention on psychotropic prescribing rates.<sup>542</sup>

Zermansky *et al.* conducted a RCT in 65 U.K. RACFs, with half the RACFs included in the intervention and the other half involved as the control. The intervention aimed to evaluate the effect of clinical pharmacist’s medication review based on the GP’s clinical record and a consultation with the patient and carer.<sup>543</sup> After six months, significant differences were found in the number of medication changes (3.1 vs. 2.4 for control;  $P < 0.0001$ ) and the number of falls (0.8 vs. 1.3 for control;  $P < 0.0001$ ). The GP acceptance rate of the recommendations was 76%. However, once again, specific information was not provided about changes made to psychotropic medication.<sup>543</sup>

In the first of three Australian studies, Roberts *et al.* in a 1995 RCT, evaluated the impact of a clinical pharmacy service provided for RACFs.<sup>350</sup> The intervention was conducted in 13 facilities in south-east Queensland and northern N.S.W., with 39 RACFs serving as control

facilities, and involved the provision of individualised medication reviews for residents as well as substantial ‘problem-based’ and pharmacological education for nursing staff of up to 11 hours per RACF. These educational sessions were supported by guidelines, telephone calls and clinical pharmacy visits, with each facility averaging 26 hours of contact over the 12 month study.<sup>350</sup>

Roberts *et al.*’s study was found to reduce overall medication use by 11% to 15%. The mean number of antipsychotics and benzodiazepines administered per resident in intervention facilities declined in comparison to control facilities, just missing out on statistical significance ( $P = 0.059$ ). However, when the data was broken down further, it was found that there was a significant decrease in the number of residents taking hypnotic benzodiazepines in intervention RACFs compared to control residents ( $P < 0.05$ ).<sup>350</sup>

Roberts *et al.* commented that the main drug categories reduced by the intervention were laxatives and psychotropic drugs, the use of which was often prompted by nursing staff. The lack of change in other medication categories was thought to reflect a stronger nursing response, rather than GP response, to the intervention. Further evidence of the poor GP response was reflected in the low acceptance rates (39%) by GPs of the clinical pharmacist’s recommendations. Roberts *et al.* ascribed the poor acceptance rate to the fact that the pharmacist had only indirect contact with GPs.<sup>350</sup>

As a consequence of Roberts *et al.* study, another RCT was funded involving 38 hostels in Queensland.<sup>544</sup> This intervention resulted in both decreases and increases in medication use which were considered to be dependent on the ‘organisational culture’ of the hostel. In those hostels that possessed an effective organisational structure that facilitated change (i.e. adequate staffing, efficient documentation procedures), there was a 13% reduction in overall drug use and a greater proportion of residents ceased benzodiazepines and antipsychotics. In addition, significant improvements were seen in quality-of life scores relating to mobility, sociability and confusion.<sup>544,37</sup> In contrast, in those hostels with a less supportive organisational structure, the intervention resulted in an increase in medication use.<sup>544</sup>

Another research project was conducted in 5 low-care hostels in Tasmania which involved monthly medication reviews conducted by a pharmacist and education for residents.<sup>545</sup> Although information on psychotropic use was not provided for this study, there was no significant difference between the number of medications used in the intervention group and the control group; however, quality of life measures in the residents belonging to the intervention group improved significantly.<sup>545</sup>

A recent study aimed to assess the impact of RMMRs on the Drug Burden Index (DBI) in a retrospective analysis of a random sample of 500 RMMR reports from 62 Sydney RACFs.<sup>446</sup> DBI scores were calculated at baseline, after pharmacist recommendations were made and

finally after GP uptake of these recommendations. A statistically significant decrease ( $P < 0.001$ ) in the median DBI score resulted from the medication review, with the authors concluding that most of the recommendations proposed by pharmacists involved withdrawing benzodiazepines or reducing antipsychotic dosages. However, it should be noted that most of these pharmacist's recommendations were not actually implemented. Only one out of four recommendations to reduce benzodiazepines, and one of three recommendations to reduce antipsychotic medications were accepted by the GP and acted upon.<sup>446</sup>

The evidence for the effectiveness of medication review to impact psychotropic rates is not robust, with only one of the RCTs outlined above showing a positive effect on reducing benzodiazepine rates of use.<sup>42</sup> This particular trial, conducted by Roberts *et al.*, also included a substantial amount of education for nursing staff, as well as promotional materials and guidelines. Additional evidence for a lack of effect of consultant pharmacist medication review services on psychotropic prescribing comes from several U.S. studies which concluded that the effectiveness of these type of services on improving the appropriateness of prescribing was limited.<sup>564,565</sup> One of the reasons for this lack of impact may be related to resistance from the GP to alter psychotropic medication, as evidenced in the Sydney DBI study.<sup>446</sup> One U.S. study reported that consultant pharmacists were making recommendations about psychotropic medication that were consistent with the OBRA-87 regulations, yet these recommendations were not taken up by GPs.<sup>599</sup> Another U.S. research team questioned if the threat of RACF sanctions resulting from the regulatory approach '*translates to influence at the level of individual physicians*'.<sup>565</sup> In any case, several studies have shown that pharmacist-led medication reviews do not appear to be effective as a 'stand-alone' intervention to improve the quality of psychotropic prescribing in RACFs. Part of this finding maybe explained by the fact they many did not actively involve the GP or the nursing staff need to be involved.

#### **19.2.6 Interdisciplinary Collaboration**

One of the more successful interventions to reduce psychotropic use was conducted in Sweden in 1995 and involved a combination of education delivered by a clinical pharmacist and monthly interdisciplinary team meetings consisting of GPs, pharmacists and nursing staff.<sup>558</sup> The year-long study included 1854 residents of 33 RACFs, with 15 facilities allocated to the intervention group and 18 facilities nominated as a control group. The intervention led to significant decreases in the prescribing of antipsychotics ( $P = 0.007$ ), benzodiazepines ( $P < 0.001$ ) and TCAs ( $P < 0.001$ ).<sup>558</sup> Reviewers have criticised the study because clinical outcomes associated with improving psychotropic prescribing were not assessed, although when surveyed, the medical staff felt that the intervention did not appear to pose any detrimental effects to the residents'.<sup>587,600</sup> A follow-up study, conducted three years after Schmidt *et al*'s

original study, found that hypnotic rates of use continued to decline after the intervention study was completed. Importantly, a significant difference was still observed in benzodiazepine prescribing rates between intervention and control facilities. On the other hand, antipsychotic prevalence in the intervention facilities had returned to pre-trial levels.<sup>601</sup>

Other interdisciplinary interventions aimed at improving the medication use in RACFs have also used the strategy of a case conference (Table 54). King and Roberts carried out a controlled study where residents of 3 RACFs had three 30 minute case conference reviews, in which GPs, nursing staff and the resident or their representative, attended. This particular intervention did not result in any significant change to medication use, costs and mortality.<sup>52</sup> However, only a third of the recommendations (53 out of 158 recommendations) made by the committee were actually implemented.<sup>52</sup> Another Australian study conducted by Crotty *et al.* evaluated the impact of interdisciplinary case conferences on RACF psychotropic use.<sup>51</sup> A total of 154 residents in five RACFs with medication issues and/or challenging behaviours were discussed in two case conferences involving the resident's GP, a geriatrician, pharmacist, nursing staff and a representative from Alzheimer's Australia, with the conferences conducted 6-12 weeks apart. The intervention resulted in a significant difference in the reduction of MAI scores for benzodiazepines ( $P < 0.01$ ) between control and intervention groups but no significant effect on resident behaviour or cost.<sup>51,602</sup> Loganathan *et al.* in his review of interventions to improve RACF prescribing argues that the reason why this study was more effective than King and Roberts' study was because the GP facilitated the case conferences and adopted responsibility for initiating the medication changes.<sup>51,602</sup>

A final example of an intervention adopting an interdisciplinary approach was conducted in a U.S. RACF and involved the use of a customised quality indicator tool, the 'Psychotropic Assessment Tool' or 'PAT', to document the behaviour and medication regime of each resident.<sup>603</sup> An important section of the PAT was a section for residents, relatives or staff to list any concerns about medications.<sup>603</sup> The 'PAT' was then discussed at a 30 minute quality assurance meeting which included the medical director of the RACF, the nursing director, pharmacist, social worker and other nursing staff. Notably the resident's GP was not present at the meeting. Instead, the completed PAT was faxed to the GP who then returned the form to the RACF with any suggestions for change. Not surprisingly, this intervention did not result in significant changes to psychotropic rates of use.<sup>603</sup> This is most likely due to the fact that the resident's GP was not actively involved in the process. Curiously, the investigators did not collect data to determine whether or not GPs followed the recommendations in the 'PAT'. A recent Cochrane Review and the research studies presented in Table 54 indicate that interdisciplinary approaches offer potential to be an effective way to reduce psychotropic use in RACFs.<sup>604</sup> However, it is important to note that the GP should be integral to the process.

**Table 54: Summary of studies that have employed interdisciplinary approaches to address inappropriate prescribing in the RACF setting**

<b>Reference</b>	<b>Setting</b>	<b>Trial design</b>	<b>Design and components of the intervention</b>	<b>Outcomes</b>
<b>Schmidt et al 1998<sup>558</sup></b>	33 RACFs, Sweden	Randomised Controlled Trial (RCT)	Pharmacist-led interdisciplinary meetings	Significant reduction in antipsychotic prescribing rates (-19%) Significant reduction in hypnotic prescribing (-37%)
<b>Schmidt et al. 2000<sup>601</sup></b>	33 RACFs, Sweden	Controlled Trial (CT)	Follow-up of first intervention	Hypnotic use declined in 3 years following intervention
<b>King and Roberts 2004<sup>52</sup></b>	3 RACFs, Australia	CT	Sessions of 3 case conference reviews	Non-significant reductions in medication orders, cost and mortality
<b>Crotty et al 2004<sup>51</sup></b>	10 RACFs, Australia	RCT	Two case conferences involving a interdisciplinary team for each resident	Significant reduction in MAI with no change in resident's behaviour
<b>Dahl et al 2008<sup>603</sup></b>	1 large RACF, U.S.	Retrospective Review	Use of 'Psychotropic Assessment Tool' (PAT) and monthly interdisciplinary meetings	Non-significant reduction in antipsychotic and anxiolytic use. Non-significant increase in hypnotic use



### **19.2.7 Reviews of interventions to promote appropriate prescribing in RACFs**

No fewer than four review articles on interventions to optimise medication use in RACFs have been published since 2008, with each reporting mixed findings.<sup>87,587,600,602</sup> Overall, the most evidence exists for interventions which educate, with more successful studies having good GP attendance.<sup>602</sup> Interventions that focus on interdisciplinary cooperation and direct communication between pharmacists, GPs and nurses appear to exert a greater impact than pharmacist-led medication review interventions alone.<sup>600,602</sup> Three of the reviews concluded that a combination of strategies may be the most effective way to improve prescribing.<sup>68,600,602</sup> Two reviews emphasised that research was sorely needed to provide evidence of benefit from reducing inappropriate medication on resident clinical outcomes and cost benefits.<sup>87,587</sup>

To sum up the findings of these literature reviews; the key elements of successful interventions to promote quality use of antipsychotic and benzodiazepine medication in RACFs should be:

- Interdisciplinary, involving all the health professionals involved with drug use;
- Multifaceted, involving a combination of several strategies, including medication audit and feedback, case conferencing and the development of practice guidelines;
- Focused principally on nursing staff whose involvement is crucial for success; and
- Educationally and guideline based.<sup>87,587,600,602</sup>

### **19.3 Roles for pharmacists in improving the quality use of antipsychotics and benzodiazepines in RACFs**

The various intervention studies outlined above show that pharmacists have the potential to play many roles in promoting the quality use of medication in RACFs. Apart from the traditional supply role, pharmacists perform RMMRs, have the potential to be an active member of the interdisciplinary team and can educate GPs, nursing staff and other members of the health care team about medication related issues. The participation of a pharmacist in collaboration with other health care providers encourages a shared approach to decision making, potentially improving health outcomes.<sup>605</sup> Yet, research evidence relating to the pharmacist's role in this setting is limited. In a recently published review of pharmacists' interventions for optimisation of medication use in RACFs only seven RCTs were included, despite the fact that clinical pharmacy services originated in the U.S. over 30 years ago and have been funded in Australia for 14 years.<sup>600</sup> Nishtala *et al.*, in their review of the impact of interventions on psychotropic drug use proposed that one way to improve psychotropic medication use was for pharmacists to work as integral members of mental health teams serving RACFs.<sup>68</sup> This is one way to utilise the knowledge of pharmacists; however, another role for pharmacists has also been suggested. In the U.S., a small pilot study was conducted to evaluate a pharmacist-based consulting service

for the management of BPSD in a RACF setting.<sup>606</sup> The site for the pilot project was a 120 bed RACF in Texas. A total of 22 residents with BPSD were identified, of whom 12 residents participated in the novel pharmacist-led program. After medical causes for BPSD were ruled out and non-pharmacological strategies trialled, 11 of the residents were started on pharmacotherapy by the pharmacists, after GP consultation. Clinical pharmacists rated the BPSD symptoms of the residents with the 'BEHAVE-AD' scale at baseline, and, again, one month after therapy was initiated. Nine of the residents were prescribed antidepressants and two residents started quetiapine. BEHAVE-AD scores decreased by at least 30% in 9 of the residents and the service was well received by the nursing staff and doctors.<sup>606</sup>

Despite participation of pharmacists in RMMRs and provision of QUM services in Tasmanian RACFs, the first stage of this research found high rates of antipsychotic and benzodiazepine use, with a low rate of dosage variation of these agents. In the second stage, pharmacists conducting RMMRs admitted that they did not make recommendations to review these types of medications, mostly due to resistance they had encountered to suggestions to reduce them. Likewise in many of the intervention studies outlined earlier, pharmacists around the world experienced similar difficulties getting GPs to implement their recommendations to review and reduce psychotropic medication. If RMMRs are not a successful way to achieve reductions in psychotropic prescribing then perhaps the associated QUM services can offer a more effective approach.

Pharmacists are ideally placed to have a positive impact on the quality of psychotropic use in the RACF setting. However, there appear to be limitations within the existing system of pharmaceutical care provision to RACFs that restrict pharmacists from adopting this role. Although pharmacists are remunerated to provide QUM activities for RACFs, it is not currently known whether they include any activities focused on appropriate psychotropic use?

The National Prescribing Service (NPS) has two clinical audits on antipsychotics and benzodiazepines that are available for pharmacists to use.<sup>607,608</sup> In addition, many medication blister-packaging programs used to package medication for residents in RACFs, offer a function to perform psychotropic medication audits. Further research is needed to evaluate if pharmacists are assisting RACFs to audit their psychotropic use.

A recent evaluation of the current Australian RMMR and QUM system was conducted by Campbell consulting in 2010.<sup>55</sup> Half of nursing staff surveyed said that they had not actually received a drug audit from a pharmacist in this time.<sup>55</sup> It was noted that some directors of nursing were '*almost entirely unaware of what they could and indeed, should, anticipate from the accredited pharmacist and what services they could request*'. This lack of awareness often led to a poor provision of QUM service.<sup>55</sup> Another important role of pharmacists suggested as a 'QUM' activity for RACFs is the provision of education about medication to nursing staff and

other members of the health care team. In the Campbell evaluation, when accredited pharmacists were surveyed, over 80% said they had provided in-service sessions for disease state management to a RACF in the last 12 months. It should be noted that, when nursing staff were surveyed, a quarter of RACFs had not received any in-service education from pharmacists in this period, and in rural areas this figure was significantly lower.<sup>55</sup> It appears that a substantial proportion of RACFs are missing out on educational sessions provided by pharmacists. Whether the topic of behavioural and psychological symptom management is covered in these educational sessions is not known.

#### **19.4 Aims and objectives of the ‘RedUSE’ intervention trial**

Judging from the first two stages of this research, the current system of RMMR and QUM provision in Tasmanian RACFs does not appear to be impacting psychotropic prescribing. Yet, some interventions have shown to be successful at reducing and promoting the appropriate use of psychotropic medication, including educational approaches, interdisciplinary collaboration and audit and feedback. A coordinated series of these types of QUM strategies is needed that specifically aims to promote the quality use of psychotropic medications in the RACF setting. Pharmacists are currently funded to promote quality use of medications in RACFs. The medication advice and service that pharmacists already provide are well accepted by the nursing staff at RACFs and by many GPs.<sup>55</sup> For this reason, pharmacists are ideally placed to co-ordinate and provide the targeted psychotropic QUM strategies suggested.

The intervention trial for this thesis was entitled the **‘RedUSE’ (Reducing the Use of Sedatives)** project. It is the first Australian intervention trial to assess the effectiveness of pharmacist-led QUM strategies in promoting appropriate psychotropic medication use in RACFs. If the project succeeds in achieving a successful reduction of prevalence rates and decreases in doses of psychotropic medication there are likely to be multiple flow-on benefits for older residents, including increased mobility, decreased fall rate and improved well-being.<sup>396</sup>

The RedUSE project was designed to address the need for a co-ordinated package of QUM strategies, including audit and feedback cycles, staff education and interdisciplinary collaborative review, that equips and trains community pharmacists to promote appropriate antipsychotic and benzodiazepine use in RACFs. The RedUSE project was also designed to be interdisciplinary, multifaceted and educational in content, recognising that intervention projects were more likely to be successful if they involved nursing staff, GPs and pharmacists, and included several strategies, in particular the education of nursing staff.<sup>87</sup> Research is also lacking on the benefits of interventions in reducing psychotropic use in RACFs and on health care costs.<sup>87</sup> For this reason, several post analyses were conducted to assess the effect of ‘RedUSE’

on the clinical outcomes of falls and challenging behaviour and a basic costing analysis was sought to evaluate the potential healthcare cost savings of the project.

The term ‘sedatives’ was adopted in this project as a more understandable or ‘layman’s’ term for antipsychotic and benzodiazepine medications. The on-line medical dictionary, ‘MedTerms’ definition of the term ‘Sedatives’ is : *‘A drug that calms a patient down, easing agitation and permitting sleep’*.<sup>281</sup>

### **19.5 The Key Objectives of ‘RedUSE’**

The key objectives of this final stage of the thesis, the ‘RedUSE’ project were as follows:

- The main objective of the RedUSE project was to promote the quality use of benzodiazepines and antipsychotics in RACFs. To achieve this objective, the ‘RedUSE’ project aimed to develop, trial and evaluate a co-ordinated intervention program delivered by community pharmacy that specifically targets the use of these medications.
- The community pharmacists were provided with a well-developed package of QUM services addressing the use of antipsychotics and benzodiazepines in RACFs. The key strategies involved audit, nursing education, and a dedicated ‘sedative review plan’. A key objective of ‘RedUSE’ was to equip pharmacists, in particular, pharmacists who were not accredited, with the generic skills and expertise to effectively deliver QUM services, which can be subsequently applied to many other therapeutic areas. The strategies of the project were primarily targeted at RACF nursing staff.
- A third objective of the RedUSE project was to evaluate its impact thoroughly. The main outcome measures of the RedUSE project were the proportions of residents taking antipsychotic and benzodiazepine agents in the participant RACFs. However, variation in psychotropic rates of use alone is not enough indication of improvement in psychotropic management in aged care facilities.<sup>39</sup> Information is also needed on the appropriateness of psychotropic use, the extent of dose reduction of antipsychotic and benzodiazepine medications in residents and the percentage of new prescriptions for these medications. Additionally, the efficacy of the nurse training requires evaluation, as does the cost benefit of the intervention. Further, it is important to gauge the overall acceptance of the project by key participants; in this case, the pharmacists and the nursing staff working at the RACFs.
- The last key objective of the RedUSE project was to gauge the effect of the intervention on the residents themselves by examining its impact on clinical outcome measures, specifically, the rates of challenging behaviour and falls. Finally, it was important to assess the long term effect of ‘RedUSE’ by conducting a follow-up study, 12 months after the trial was completed, to evaluate if the intervention had any lasting impact on the use of psychotropic medication in participant RACFs.

## CHAPTER TWENTY: METHOD

### AN INTERVENTION TO IMPROVE QUALITY PSYCHOTROPIC USE IN RACFS

#### **20.1 Study design**

The cross sectional retrospective prevalence study in the first stage of this thesis provided information on psychotropic use which was used to calculate the number of RACFs required for the intervention study to be sufficiently powered to detect statistical significance. To detect a 10% reduction, with an average benzodiazepine prevalence rate of 42% of residents (SD 8), a total of at least 12 RACFs were required in each group for a pre and post-intervention comparison (at a power of 80%;  $p = 0.05$ ).

The study design was a controlled trial conducted in 25 RACFs in Tasmania. The intervention group included 13 Hobart RACFs and the 12 control RACFs were located in Launceston (the two cities are geographically 180 km apart). This trial structure was chosen as it was thought likely that if intervention and control aged care facilities were in the same locality, pharmacists, nurses and GPs involved with intervention facilities may service control RACFs as well, with the associated risk of intervention information spreading to control facilities and causing contamination of the control sites. After recruitment, the two groups were statistically compared to ensure matching of baseline variables. In order to gauge the level of RMMR and QUM pharmacy services provided to each RACF group, each participant pharmacy was also asked to provide data regarding the number of RMMRs conducted six months prior to, and during, the RedUSE trial. Community pharmacies were also asked to provide details about the QUM strategies provided to each RACF throughout 2008.

#### **20.2 Outcome measures**

The primary outcome measure in the RedUSE project was the RACF prevalence rates of regular use of antipsychotics and benzodiazepines. It is important to acknowledge that the RedUSE project was targeted at the facility level and that the outcome measures were all RACF rates of psychotropic rates of use, not grouped individual rates of use. Secondary outcome measures were:

- Prevalence rates of psychotropic agents overall
- Multiple psychotropic rates
- Antidepressant rates
- Potentially inappropriate psychotropic rates (according to the modified Beers criteria and the U.S. Long-term Care Facility interpretive guidelines).

- The number of dosage reductions/cessations of antipsychotics and benzodiazepines
- The variance in the dosage equivalents of chlorpromazine and diazepam
- The number of new antipsychotic or benzodiazepine agents initiated throughout the trial.

All outcome measures were obtained from a psychotropic medication audit of community pharmacy dispensing records conducted in all participant RACFs. The clinical audit measurements were performed at baseline, three months and 6 months after trial commencement.

Cholinesterase inhibitors such as donepezil, anticonvulsants and clonazepam can be prescribed for their sedative effects but were excluded from the psychotropic measures as the indication for use was often uncertain. Cholinesterase inhibitors are more commonly prescribed as cognitive enhancers rather than to treat BPSD and anticonvulsants and clonazepam are also indicated for seizure control. Clozapine and lithium carbonate were also excluded from analysis as these agents are restricted for schizophrenia and/or bipolar disorder management, with dose reduction and non-drug therapy not generally promoted.

### **20.3 Data collection**

Personally collecting prescribing data from 25 RACFs would be very time and labour time intensive. As time and staff to collect data are in short supply in both RACFs and community pharmacies, alternative methods of data collection were sought. A dedicated computerised medication audit tool, referred to as the 'RedUSE psychotropic audit program' was developed as an integral part of the project. The research team were aware through previous research project experience that detailed information about medication utilisation already existed within community pharmacy dispensing programs. Consequently, a computer programmer designed a program to specifically access or 'mine' psychotropic medication data. This program was designed to be similar to an existing program termed 'NHDMS' which assimilated community pharmacy RACF dispensing information from the 'Webstercare Meditrax'® medication packing program. Community pharmacies supplying RACFs use these packing programs to prepare and label resident medications into individualised blistered packs, which are delivered to the facilities and subsequently administered to residents by nursing staff. The customised 'RedUSE' psychotropic audit computer program also assimilated community pharmacy RACF dispensing information from 'FredPak'®. Both medication packing systems are used extensively by community pharmacies in Tasmania.

The RedUSE psychotropic audit program was installed at each community pharmacy supplying the participating RACFs in both intervention and control facilities and efficiently

collated information about psychotropic prescribing. If the medication was prescribed as a 'prn' medication, or if liquid and 'quickmelt' preparations were supplied to RACFs outside the blisterpacks, most of the pharmacies omitted to record these medications in the packaging programs. For this reason each of the resident's medication charts were checked by the pharmacists at RACFs to identify any 'prn' or liquid/quickmelt preparations and enter these dosing details manually into the RedUSE program. If 'prn' psychotropic agents were administered four or more days per week over the past month, they were considered to be 'regular' medication and were included in prevalence counts. A sample data entry page of the RedUSE psychotropic audit program is shown at Appendix L. The outcome measures for the project were all calculated utilising de-identified data obtained from the three RedUSE psychotropic audit program measurements conducted at each RACF. All data within the program was stored in a Microsoft Access® relational database.

An important feature of the RedUSE psychotropic audit program was its capacity to generate a five page customised report for each participant RACF. The RedUSE report not only listed psychotropic prevalence rates but the program also 'benchmarked' results graphically alongside antipsychotic and benzodiazepine prevalence rates reported in the most recent Sydney study and the first Tasmanian prevalence study in stage two of this thesis.<sup>90</sup> A RedUSE psychotropic audit report was produced for each participating RACF, both intervention and control facilities after each measure was conducted. A sample page from the report is attached at Appendix M.

The RedUSE project's RACF baseline audit measurements were taken mid-August to early September 2008, the three month measure was taken during November 2008, with the last 6 month measurement completed in late February 2009.

#### **20.4 Recruitment of participants**

After ethical approval was granted by the Tasmania Health and Medical Human Research Ethics Committee in April 2008, Directors of Nursing (DONs) of RACFs in Hobart (n = 27) and Launceston (n = 19), were invited to participate in the RedUSE project. Two specialised RACFs, one catering for dementia patients with challenging behaviour and the other for patients with severe mental health and drug abuse issues, were excluded as these facilities were known to have disproportionate use of psychotropic medication and the residents at these facilities were also closely monitored by specialist health professionals from the Tasmanian Department of Health and Human Services Older Persons Mental Health Service.

When an RACF expressed interest in participating, the manager of community pharmacy supplying medications to the facility was then approached by the research team and invited to participate. Facilities serviced by more than one pharmacy, and pharmacies not employing a

computerised medication packaging system, were excluded due to the data collection methodology. Both the DON of the RACF and its community pharmacy manager were required to agree to participate before the facility was accepted into the project. Recruitment continued until sufficient numbers of RACFs entered the trial. After permission to participate in the RedUSE trial was obtained, the author visited each of the facilities and community pharmacies during May and June 2008 to outline the key strategies of the 'RedUSE' project to management representatives. The 25 participant RACFs were recruited by mid-June 2008.

### **20.5 Advisory committee**

The RedUSE project was a collaborative, interdisciplinary program involving various professional bodies in the planning and operational phases. An advisory committee was established for 'RedUSE' in April 2008, involving key representatives from the University of Tasmania, the RACF sector, Alzheimer's Australia, consumer groups, the local Division of General Practice, the Tasmanian Pharmacy Board, the Pharmaceutical Society of Australia (Tasmanian Branch), Pharmaceutical Services (Department of Health and Human Services) and the Pharmacy Guild (Tasmanian Branch). The role of this committee was to provide input on the project strategies and facilitate the delivery of 'RedUSE' to RACFs. The Advisory Committee met on four separate occasions during the development of the project.

The RedUSE Advisory Committee was directly responsible for the modification and introduction of one of the project's key strategies; the 'Sedative Review Plan' form. Initially the research team proposed that community pharmacists set up interdisciplinary case conferences to discuss and review the medication of those residents taking sedative medication for extended periods; a strategy choice based on the success of several intervention models overseas.<sup>558,582</sup> However; members of the Advisory Committee were not supportive of this proposal. Mindful of current GP and nursing staff shortages, the committee felt it was not feasible to set aside a period of time where the three health professionals could meet in the majority of RACFs. The Nursing and GP representatives on the committee put a strong case forward for the research team to reconsider this strategy. As an alternative to conference meetings, a paper-based 'sedative review plan' form was proposed where pharmacists, nursing staff and GPs could each comment on the sedative use of a particular resident. This revised strategy of a 'sedative review plan' was approved by both the RedUSE Advisory Committee and the Ethics Committee.

### **20.6 Intervention strategies**

A flowchart illustrating the key strategies of the RedUSE project utilised in all intervention RACFs is shown in Figure 15 overleaf. The main strategies of the RedUSE project were 1) its computerised psychotropic audit program with associated feedback and benchmarking provided



to RACF nursing staff, 2) two staff educational sessions and 3) the interdisciplinary sedative review plan prepared for each resident receiving long-term antipsychotic or benzodiazepine therapy. The community pharmacy supplying the RACF was directly responsible for the provision of all three main ‘key’ strategies of RedUSE to intervention facilities.

Other supporting strategies of the RedUSE project involved guideline development and promotion, academic detailing of GPs, newsletters and resident and relative information pamphlets. These ‘secondary’ strategies were delivered or provided by the research team.

### **20.6.1 Guideline development and distribution**

At the project’s onset, RedUSE Guidelines were produced with the assistance of a local geriatrician and psychogeriatrician. These guidelines (Appendix N) were based on recommended best practice for antipsychotic and benzodiazepine use from the IPA, the Faculty of Psychiatry in Old Age and the RACGP.<sup>94-96</sup> The ‘RedUSE’ guidelines were designed to be clear and concise, and practice suggestions for reducing psychotropic medication doses were included. The Guidelines were initially prepared by the researcher and then sent to the specialists for their input. All suggestions made by these two specialists were incorporated into the guidelines and they were promoted as ‘local guidelines’ that had been endorsed by Hobart specialists in the field of old age psychiatry and geriatric care. The guidelines were used extensively throughout the whole project. These guidelines were sent to all GPs and pharmacies involved with the intervention RACFs and several sets of laminated copies were sent to the intervention RACFs themselves. At the pharmacist training, the nurse educational sessions and during academic detailing sessions, the guidelines were discussed and reinforced.

### **20.6.2 Consciousness-raising activities**

One of the first aims was to attach an identity to the proposed intervention project through the creation of a recognisable ‘acronym’ and ‘logo’ for the project. Figure 16 below illustrates the RedUSE logo selected. The colour (duck-egg green – very fashionable in 2008) and the design of the logo were specifically selected to appeal to nursing staff so they would be able to readily relate to the intervention.

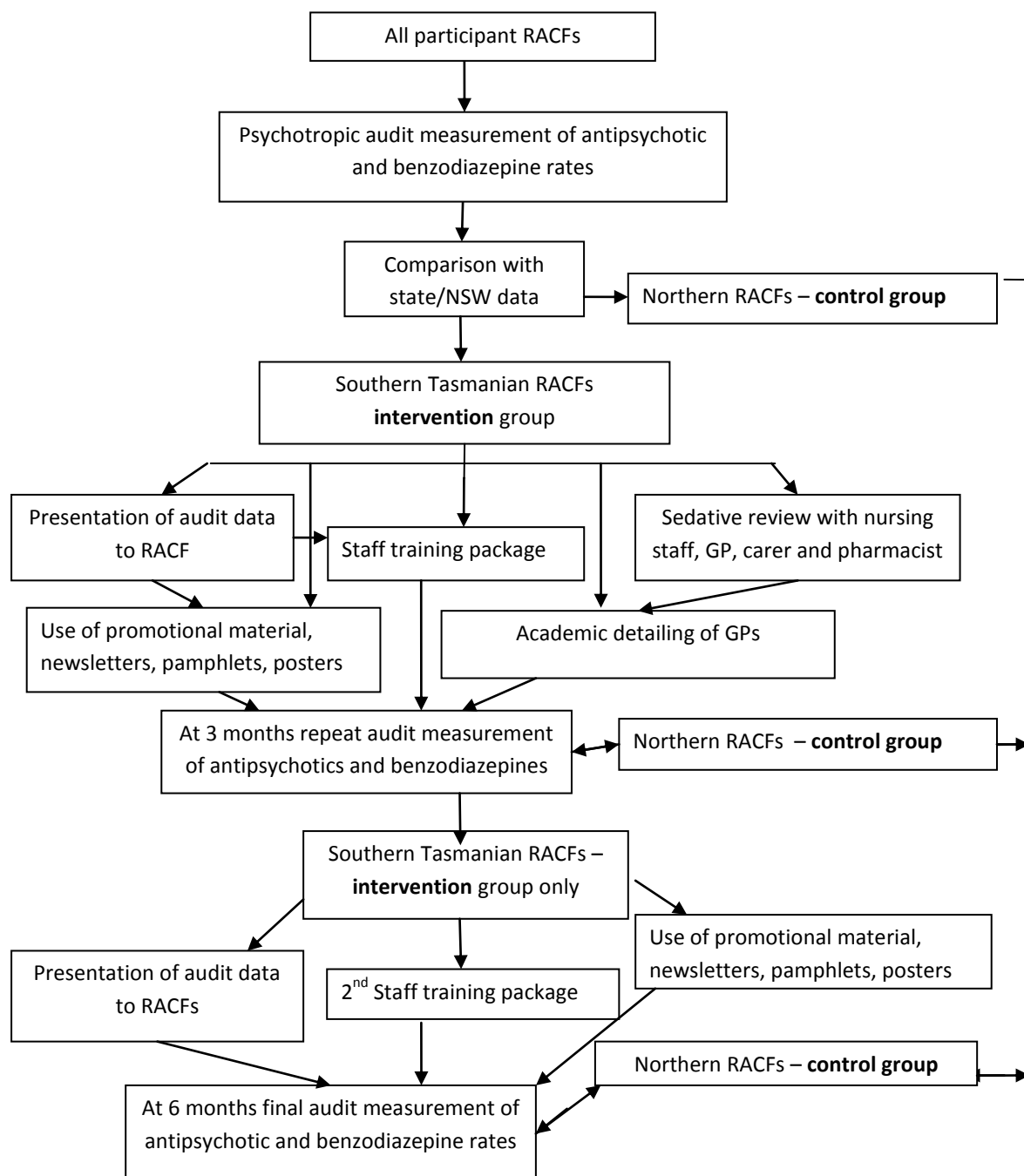
**Figure 16: The ‘RedUSE’ logo**



Leaflets regarding the RedUSE project were distributed at a large conference for RACF staff held by Alzheimer's Australia in Hobart in January 2008. Over 200 nursing staff from Tasmania's RACFs attended the two day event. A total of 100 fliers outlining the project were distributed to attendees. The local Divisions of General Practice in Hobart and Launceston were also informed about the project.

All of the intervention RACF DONs and RNs in charge of clinical services, participating pharmacists, GPs serving these RACFs and advisory group members were invited to the official launch of the RedUSE project, which adopted an evening seminar format. At this event the project was introduced and a guest speaker, leading psychogeriatrician, Professor John Snowdon, presented information about best practice use of antipsychotics and benzodiazepines in RACFs. Professor Snowdon also discussed the reduction of benzodiazepine use which had occurred in Sydney RACFs over the past decade.<sup>90</sup> A total of 91 health professionals attended the launch; specifically, 18 GPs, 31 pharmacists and 42 nursing staff. All intervention RACFs and community pharmacies were represented. Continuing Professional Educational (CPE) recognition was applied for, and granted by, the Pharmaceutical Society of Australia (PSA) and the RACGP. Nursing staff were advised to record the event in their continuing education register. All attendees were asked to complete an evaluation form at the conclusion of the evening. It should be noted that a press release was sent out before the event and Professor Snowdon was interviewed on local radio about the RedUSE initiative where he mentioned the large disparity in benzodiazepine use between Sydney and Tasmania.

**Figure 15: The ‘RedUSE’ trial strategy implementation flowchart**



### **20.6.3 Education of participant pharmacists**

Community pharmacists from the participating community pharmacies entering the intervention arm of the study received one and a half days of education in July 2008. The educational sessions were delivered by the RedUSE research team and several guest presenters, notably, the Director of Aged Care and Rehabilitation Medicine at the Royal Hobart Hospital, the Director of Nursing at an RACF specialising in the management of BPSD and a psychiatrist at the Hobart Alcohol and Drug Service. The first day covered antipsychotic and benzodiazepine therapeutics and also reinforced recommended best practice for the management of challenging behaviour in dementia and sleep disturbance. On the second day, pharmacists were given instruction on the strategies of the psychotropic audit cycles, delivery of nurse education and the sedative review plan. A local GP, Director of Nursing at one of the RACFs and an accredited consultant pharmacist also discussed potential enablers and barriers of the project with the participant pharmacists in a panel style format.

A key part of the training program for the pharmacists was to have a frank and open discussion about the use of antipsychotic and benzodiazepine medication to manage behavioural and psychological symptoms in older people in RACFs. One of the findings of the qualitative stage of this thesis was that the attitudes and beliefs of health professionals about the use of antipsychotics and benzodiazepines affect their prescribing and review. Education about geriatric pharmacology and other geriatric topics has also been shown to positively influence the attitudes around the use of these medications. One of the aims of the pharmacist training program was to encourage the pharmacists to have similar discussions about the use of these medications with nursing staff at the RACFs when they delivered the educational sessions. Nine hours of CPE recognition was allocated for the training by the Pharmaceutical Society of Australia and the pharmacist training program was evaluated by a short questionnaire that the pharmacists were asked to complete. The full pharmacy training program schedule is attached as Appendix O).

### **20.6.4 Educational strategies of RedUSE**

Two educational sessions, each lasting an hour, were developed for the nursing staff at the intervention RACFs by university educators and these were reviewed by an experienced external reviewer (See Appendix P). The nine trained community pharmacists from the RACF supply pharmacies delivered each of these educational sessions to the intervention RACFs. The first educational session was scheduled at each facility approximately 2-4 weeks after the baseline RedUSE psychotropic audit measure was taken. The pharmacists delivered all nursing staff education at the RACFs guided by a Microsoft PowerPoint® presentation developed by the research team. Aside from promoting evidence-based use of antipsychotics and

benzodiazepines, the individual psychotropic audit results for each facility were presented as part of the session. Open discussion between the nursing staff members about the perceived effectiveness of sedative use was sought and encouraged. A filmed case study about dementia that was available from the PSA was also included as part of the presentation.<sup>609</sup> Pharmacists presenting the RedUSE educational session reported that the first session was of 40 minutes to an hour's duration.

The second educational session was held 2-4 weeks after the second psychotropic audit measure (performed at 3 months). This session re-enforced information from the first session and the results of the second follow-up audit were presented to staff, as in the first session. The second session was a little shorter than the first session, with a recorded duration of 30 to 45 minutes.

An evaluation of all the educational programs of RedUSE was performed by asking participants to complete evaluation forms in the format of an anonymous survey utilising a standard visual analogue questionnaire. In order to gauge the effectiveness of the nursing staff education, a ten item multiple-choice question 'old age mental health-psychotropic' (OAMHP) educational knowledge quiz was devised and validated before use and the process is outlined in Chapter 20. This 'psychotropic quiz' was devised as a simple means to evaluate the baseline knowledge of the nursing staff on the pharmacological management of behavioural and psychological symptoms in older people. Currently, there are no validated standardised questionnaires available to assess nursing staff knowledge in this particular area. The nurses were asked to complete the quiz at the beginning of the first nurse educational session and the same quiz was completed at the end of the second session. All nurses were asked to complete the quiz anonymously but participants were coded to allow matching of results from the pre and post quizzes.

The GPs providing services to the intervention RACFs were ranked according to the number of residents they provided medical services for. GPs responsible for eight or more residents in intervention RACFs were invited to participate in an academic detailing session with a researcher. A total of 17 GPs out of 32 GPs approached, participated in this single session, lasting 10 to 15 minutes, where 'good practice' principles for antipsychotic and benzodiazepine use in older people and the key strategies of the RedUSE project were outlined. Other educational/promotional materials included three customised RedUSE newsletters which were distributed to all intervention RACFs and steering group members every two months, and educational pamphlets for relatives and residents about benzodiazepines. The RedUSE newsletters contained guideline-based information about antipsychotics and benzodiazepines, details of the latest research in the management of old person's mental health conditions and also gave additional feedback to participant RACFs regarding project outcomes. Each of the

one-page, double-sided RedUSE newsletters was reviewed by research staff and an external reviewer. A sample page of the newsletter is attached as Appendix Q.

The resident and relative pamphlets presented information about the problems associated with long term use of benzodiazepines and also included guidance on alternative methods to manage sleep disturbance and anxiety in clear, non-medical language. The educational pamphlet was developed in conjunction with Alzheimer's Australia, a clinical nurse at a RACF not involved with the project and a consumer representative. A page of the pamphlet is attached as Appendix R.

#### **20.6.5 Sedative Review Plan Forms**

One of the QUM strategies proposed for the RedUSE project was interdisciplinary case conferencing. It should be noted that case conferences are an established, Medicare funded 'enhanced medical service' for GPs. Case conferences must include a GP and at least two other health care providers.<sup>54</sup> Consent is not required from a resident or their enduring guardian (usually a relative) to discuss the medical needs of a resident in a case conference. On the other hand, consent is legally required from the relevant party before the medical treatment of a resident is altered.<sup>505</sup> As discussed earlier, the advisory group felt that it was not feasible to schedule a time where the GP, nursing staff and pharmacist could meet face-to-face to discuss a resident's medication use. They also pointed out that interdisciplinary meetings were not only difficult to coordinate, but that many GPs were not supportive of them as they felt they offered little benefit.

As an alternative strategy, a written 'sedative review plan' form was proposed with the specific aim of encouraging interdisciplinary communication and providing a prompt for the review of individual residents' long-term antipsychotic and benzodiazepine use. The sedative review forms were intended to highlight and promote discussion about the long term sedative use of residents amongst the health professionals involved with medication use; specifically the GP, nursing staff and pharmacist. As the sedative review forms contained identifiable patient data they were not able to be analysed or sighted by the research team. This condition was emphasized in the ethics amendment granted for this revised strategy of the RedUSE project.

When the first psychotropic audit measure was conducted for intervention RACFs, the RedUSE psychotropic audit program was programmed to automatically generate an individual 'sedative review plan' for each resident prescribed regular doses of antipsychotics and/or benzodiazepines for periods longer than recommended (3 months for antipsychotics and 4 weeks for benzodiazepines). The sedative review plan outlined resident details, psychotropic doses currently taken and included three sections; one for pharmacist recommendations, another

for nurse recommendations and a final section for GP comments. The Sedative Review Plan is attached as Appendix S.

The Sedative Review Plan generated by the RedUSE program included pre-programmed comments in the pharmacist section regarding sedative medications. These comments were based on best practice use of antipsychotics and benzodiazepines. If, for example, a resident was taking benzodiazepines on a long-term basis, the pharmacist recommendation box was printed with:

***‘Tolerance develops to the hypnotic effects of benzodiazepines within two weeks. May I suggest a gradual reduction in dose as per attached RedUSE guideline sheet.’***

It should be noted that the pharmacists were given the capacity to override these comments and write their own recommendations. The sedative review plan form was generated in the community pharmacy supplying the intervention RACF. After the pharmacist added their comments, two copies of the form were delivered to the RACF where the nursing staff added their comments. One copy of the sedative review form was then filed in the resident’s notes and the other copy was sent to the resident’s GP for their assessment and comment. It should be stressed that these forms were primarily intended to highlight those resident’s in need of sedative review.

## **20.7 Statistical analysis**

Information regarding the provision of RMMRs prior to and during the RedUSE project was collected and data recorded on QUM services provided to all 25 participant RACFs. A ratio of RMMR provision was calculated for both the intervention and control RACF groups by adding the total number of RMMR services conducted throughout 2008, dividing this figure by the number of RACFs in each group, and then, finally, by dividing this number by the average number of residents in the intervention or control group.

The antipsychotic, benzodiazepine, overall psychotropic, multiple psychotropic and antidepressant prevalence rates of all participant RACFs at baseline, 3 months and 6 months were calculated, grouped and then statistically analysed. Similarly, the dosage variance, or the number of antipsychotic and benzodiazepine doses decreased, ceased, increased or unaltered, for each RACF and subsequently each trial group were calculated and statistically analysed. In addition, the number of psychotropic medications initiated and ceased throughout the trial from baseline to week 26 was examined.

To examine the dosage variance throughout the trial quantitatively, all antipsychotic doses were converted into chlorpromazine equivalents. Likewise, all benzodiazepine dosages

were converted into diazepam equivalents. The equivalent doses for psycholeptic medications were calculated using the WHO International classification of Primary Care and several other key references.<sup>131,487,610</sup> Where more than one agent in the same psychotropic class was taken by the same resident the dose equivalents were added together. Mean equivalent doses for each RACF were calculated by adding the equivalent doses of each resident together and dividing the total by the number of residents in each RACF. It should be noted that residents in each facility not taking either an antipsychotic or benzodiazepine medication were assigned a nil value.

The appropriateness of psychotropic use was assessed at baseline and then again at week 26 using the same methodology as in stage one of this thesis. The appropriateness of psychotropic use was assessed by a combination of two criteria. Firstly, as the Beers criteria is the most commonly used method in identifying potentially inappropriate prescribing in older people, the criteria specifically relating to potentially inappropriate psychotropic medications, regardless of diagnosis, were applied to the Tasmanian RACF prescribing data. These criteria were taken from the latest Beers 2003 revision (refer to Table 26).<sup>359</sup> As the Beers criteria do not provide an indication of the appropriateness of antipsychotic prescribing, or offer comprehensive geriatric psychotropic dosing recommendations, the criteria for appropriate psychotropic medication use according to the 'Centers for Medicare and Medicaid Services, interpretive guidelines for long term care facilities' were also applied to the Tasmanian RACF dataset (refer to Table 27). Some parameters of the interpretive guidelines could not be assessed as detailed diagnostic information on the residents was not available; for this reason only data on excessive dosages of antipsychotic and benzodiazepine agents was collected.<sup>409</sup>

To obtain a measure of the extent of multiple psychotropic agent use, simple prevalence counts of the use of two or more, three or more and combined antipsychotic and benzodiazepine use were performed, collated and statistically analysed.

Independent-samples t-tests and the Fishers exact test were used to determine significant differences in RACF characteristics and the appropriateness of psychotropic prescribing between control and intervention facilities. Paired t-tests and repeated measures analysis of variance (R-ANOVA) were used to test for differences in continuous level outcome variables for baseline, 3 months and 6 months comparisons between control and intervention nursing RACFs.

The dose variations of antipsychotics and benzodiazepines were tracked in those residents taking these medications at baseline and who were included in the remaining two DUE measurements. Dose variations were tested with a 2-way, chi-squared test. Chi-squared tests were also used to compare the difference between the number of residents reducing/ceasing and starting antipsychotics and benzodiazepines in the intervention and control RACF groups.



A validated old age mental health psychotropic 'OAMHP' quiz was given to nurses to complete before and after the nursing staff training sessions. This quiz was used to assess the effectiveness of the training in terms of knowledge improvement. The results of nursing staff completing the quiz before and after the educational sessions were statistically compared using a paired t-test. The pharmacist training session, two nursing staff training sessions and the initial RedUSE launch were evaluated by separate evaluation surveys.

Analyses were performed using StatView, v 5.0 (SAS Institute Inc., Cary, NC, USA) and SPSS version 18 (IBM, Chicago, IL). All tests were two-sided and  $p$ -values  $< 0.05$  were considered statistically significant.

## **20.8 Qualitative analysis**

In order to gauge the acceptability of the RedUSE project, two focus groups were held in Hobart two weeks after the final DUE measure; one with nursing staff and the other with participating pharmacists. Focus groups are a form of group interview that takes advantage of communication between research participants in order to generate data.<sup>611</sup> Focus groups explicitly use group interaction as part of the method. This means that instead of the researcher asking each person to respond to a question in turn, people are encouraged to talk to one another: asking questions, exchanging anecdotes and commenting on each other's experiences and points of view. Focus groups are particularly useful for exploring people's knowledge and experiences and can be used to examine not only what people think but how they think and why they think that way.<sup>611</sup>

To minimise bias and allow open feedback about the RedUSE project, both focus groups were conducted by an independent qualitative facilitator. The focus group interviews were recorded, transcribed by the facilitator. Analysis was performed by the researcher according to the principles of grounded theory whereby key themes are identified as they emerge from the data.

## **20.9 Costing study**

A qualified health economist was recruited in April 2009 to examine the basic costing of the RedUSE project. Details of all antipsychotic and benzodiazepine medications and doses taken by both intervention and control RACF residents at baseline and at week 26 were recorded. These medications were then costed using the PBS pricing schedule from February 2009.<sup>612</sup> The same pricing to medications at baseline and week 26 was allocated to items rather than applying the scheduled cost at the time of dispensing. This decision was made because one of the most popularly prescribed antipsychotics, risperidone, was taken off patent at the end of December 2008, resulting in a considerable drop in overall costs of several of the newer, more expensive

atypical antipsychotics. Using the actual antipsychotic costing at the time of dispensing would have overstated the potential cost benefits of the intervention.

#### **20.10 Trial registration and Ethics**

The RedUse project was registered as a controlled trial at the Australian New Zealand Clinical Trials Registry: registration number: ACTRN12608000221358 in April 2008.

Approval for the trial was granted by the Human Research Ethics Committee (Tasmania) Network in April 2008: approval number H0009858. Two amendments to the original ethics proposal were made during the course of the project. The first amendment was made to change the strategy of a case conference to the 'sedative review form'. The second amendment involved approval for the collection of clinical outcome data from the intervention RACFs and also approval for the RedUse follow-up study.

#### **20.11 Funding**

The researchers of the RedUse trial were successful in obtaining an Investigator Initiator funding grant from the Australian Government, Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement administered by the Pharmacy Guild of Australia.<sup>613</sup>

Each RACF and community pharmacy in the intervention group was paid \$1000 as a participation fee. Each pharmacist was paid \$100 to perform each psychotropic clinical audit. The pharmacists (\$100) and nurses (\$25 gift voucher) were remunerated to deliver and attend training sessions. GPs were funded \$50 to participate in a 10-minute RACF academic detailing session.

## CHAPTER TWENTY ONE: QUIZ VALIDATION

### AN INTERVENTION TO IMPROVE QUALITY PSYCHOTROPIC USE IN RACFS

#### **21.1 Background**

One of the main findings of the qualitative study in stage two of this thesis was that the level of knowledge about psychotropic medication was poor. All twenty health professionals said they rarely referred to guidelines on psychotropic medication, nor were some aware of their existence. A consistent comment was that they relied on personal experience to gauge what agent to use, what dosage to give and whether or not to review medication. So it was not surprising that many times during the interviews participants were uncertain over how long to use these medications for, the correct doses to administer for older people and what were the common side effects to look out for. Among many of the nursing staff there was confusion over whether antipsychotics or benzodiazepines were better to manage agitation and other behavioural symptoms. Some viewed these medications as interchangeable.

Knowledge about older person's mental health in the RACF setting is important on many levels. Obviously, a sound therapeutic knowledge is needed to ensure quality use of psychotropic medication. In some cases, non-pharmacological strategies may be a better alternative and they should be trialled first. If medication is required, it is important to know which medication has the most evidence to support its use, the appropriate dose and what side effects may present. Yet, increased geriatric education has been shown to offer other benefits. In a large Norwegian study, those nursing staff with additional training in geriatrics and dementia had a more positive attitude towards older people which translated into a higher quality of care.<sup>525</sup> Thus, educating health professionals about psychotropic medication and older age mental health not only facilitates better prescribing but such training offers the potential to improve the overall quality of care residents receive.

The majority of the RedUSE project strategies involve education about psychotropic medication in some form, including the pharmacist training sessions, the academic detailing of GPs and 'sleeping tablet' pamphlet for the relatives. However, the main educational component of the trial was developed for the RACF nursing staff to meet a perceived need for education about old age mental health disorders and the psychotropic medications used to treat them. Although it is well recognised that the prevalence of dementia in Australian RACFs is increasing and the majority of residents are likely to exhibit behavioural and psychological symptoms, it is not known if the nursing staff who care for these residents are equipped with the knowledge to manage them appropriately. A recent review on this topic noted that there was

limited Australian research on the mental health knowledge of nursing staff working in aged care.<sup>523</sup>

For the RedUSE intervention project, a validated old age mental health psychotropic knowledge quiz was sought in order to assess the baseline knowledge of the nursing staff. It was important to have this data so the educational sessions could be tailored to increase knowledge in areas where understanding was shown to be limited. Such a quiz was also required so that the effectiveness of the nurse training could be measured; the idea being to conduct the quiz at the beginning of the first educational session, and then repeat it after the second educational session and compare the two scores. Unfortunately, no validated old age mental health psychotropic quizzes could be found in the published literature. For this reason, the RedUSE Old Age Mental Health - Psychotropic (OAMHP) quiz was developed and validated for this purpose.

## **21.2 Aim**

*'Only after a knowledge assessment instrument has been validated can sound scientific conclusions be drawn from its results.'*<sup>614</sup> A standard psychometric methodology must be followed to ensure that a quiz is valid and reliable for testing. In theory, this process demonstrates that the results of a quiz are accurate, consistent, reproducible and stable over time.<sup>614-616</sup> The objective of this sub-study, therefore, was to develop and validate a brief self-administered quiz for the purpose of assessing nursing staff knowledge of old age mental health psychotropic medication.

## **21.3 Methods**

To be valid a quiz/questionnaire needs to meet five criteria: a) to be acceptable to the population under study; b) to be easily completed (e.g. not time consuming); c) to be consistent; d) to be reproducible when administered on two separate occasions; and e) to be of value when complete.<sup>617</sup> The RedUSE OAMHP quiz was designed with these simple criteria in mind. The quiz was primarily intended to evaluate the nurse's knowledge about what certain psychotropic medications are indicated for, the recommended duration of benzodiazepine and antipsychotic use before review and the common side effects associated with psychotropic agents. The first draft of the quiz was written by the researcher as a 12-item multiple choice test, with 11 four answer questions and one true/false question.

### **21.3.1 Content validity**

The appropriate coverage of the subject matter, in this case psychotropic medication to treat old age mental health symptoms, is called 'content validity'.<sup>618</sup> To ensure content validity, the quiz was initially devised by the researcher after she completed a considerable literature review on

the topic and also consulted with two local specialists; one a geriatrician, and the other an old age mental health psychiatrist. This draft quiz was then checked and ‘tested’ by two experienced pharmacy academics. Several of the questions were considered repetitive by one of the academics so were removed and the other academic changed the phrasing of two of the questions to be less ambiguous. The quiz was then sent to the nursing staff member of the Advisory Committee who was a DON of a RACF not involved in the RedUSe trial. She distributed the quiz among a small select sample of her nursing staff. Of 2 RNs and 4 ENs who completed the revised OAMHP quiz, one of the ENs felt that the meaning of one of the questions was unclear, so this question was subsequently reworded and re-checked with the same EN. All of the other nursing staff commented that they were satisfied with the types of questions asked and they thought they were relevant to their practice. They also commented that they were pleased with the one page format of the quiz and said that it only took a few minutes to complete. The final version of the OAMHP quiz is shown as Figure 17 overleaf.

### **21.3.2 Construct validity**

In the absence of other quizzes or knowledge scales to compare the quiz to, ensuring content and construct validity are considered appropriate methods to develop a knowledge instrument such as a quiz.<sup>616</sup> ‘Construct validity’ determines the instrument’s ability to function for its intended purpose.<sup>614</sup> The ‘contrasted groups’ method was employed to determine the construct validity of the quiz. It was hypothesized that if the OAMHP quiz was a valid measure of old age mental health psychotropic knowledge, accredited pharmacists reviewing these medications and academic pharmacists with a high degree of therapeutic knowledge should achieve significantly higher scores than third year undergraduate pharmacy students who had not performed medication reviews or worked in RACFs. It was also hypothesized that the scores for the third year pharmacy students would be significantly higher than first year pharmacy students who had not covered therapeutic topics in any depth, especially mental health. To confirm this hypothesis, the OAMHP quiz was administered to three groups of subjects: accredited pharmacists/academics; third-year pharmacy students, and first-year pharmacy students. Content validity would be confirmed if the mean OAMHP test scores between groups were significantly different.

**Figure 17: The old age mental health psychotropic (OAMHP) quiz for nursing staff**

Participant Number: \_\_\_\_\_



**Anonymous pre-educational quiz for nursing staff**

*Could you please complete this quiz to allow for evaluation of the RedUse staff education package. Your presenter will allocate you a number before you start this quiz. (please write your number in a diary or enter it into your mobile)*

I work as a:                      EN                      RN                      (Please circle answer)

1.      **Risperidone is most effective for the treatment of which behaviour of concern?**  
a. calling out      b. wandering      c. aggression      d. repetitive questioning
2.      **The maximum recommended daily dose of risperidone in older people with dementia is:**  
a. 2mg                      b. 1 mg                      c. 4mg                      d. 3mg
3.      **Which of the following side effects has not been associated with the use of olanzapine?**  
a. stroke                      b. falls                      c. elevated blood sugar      d. hyperthyroidism
4.      **Regular trials of reducing antipsychotic doses in residents with dementia should be performed every:**  
a. month                      b. 3 months                      c. 6 months                      d. 12 months
5.      **The drug diazepam is mainly indicated to treat:**  
a. depression                      b. behaviours of concern      c. infection      d. anxiety
6.      **Which of the following side effects is not commonly associated with benzodiazepine use?**  
a. falls                      b. memory impairment      c. nausea      d. confusion
7.      **What is the recommended duration of benzodiazepine treatment for sleep disorder or anxiety?**  
a. 2 - 4 weeks                      b. 6 weeks                      c. 3 months                      d. 6 months
8.      **The first-line medication treatment for depression in older people is:**  
a. amitriptyline      b. a SSRI (e.g. citalopram)      c. risperidone      d. oxazepam
9.      **Tricyclic antidepressants, such as amitriptyline and doxepin, are recommended as a night time sedative.**  
True                      False                      (please circle correct answer)
10.      **Oxazepam belongs in which psychotropic drug group?**  
a. antidepressant      b. anticonvulsant      c. anxiolytic      d. antipsychotic

**21.3.3 Re-test reliability**

Reliability/reproducibility is also a vital attribute of a sound knowledge instrument.<sup>616</sup> An instrument is said to be reliable when scores are consistent over time and the variability of the instruments results are due to true differences among the individuals being measured.<sup>619</sup> For this reason the test-retest method was utilised to demonstrate the reliability of the OAMHP quiz over time. A subset of the third year students (15 students) repeated the quiz 8 weeks after

filling in the quiz, a time period considered sufficient to reduce the impact of recall, yet not too far apart that the student's mental health knowledge might have changed.<sup>618,619</sup> A quick check was made that the students were not covering mental health topics in depth at university. The two sets of quiz results for each student repeating the quiz were compared with the Wilcoxon Signed Rank test. A Spearman Rank correlation coefficient was calculated between the quiz scores from each test. These two tests were used as the data was non-parametric. A correlation coefficient of 0.80 or higher is considered acceptable for demonstrating test-retest reliability.<sup>619</sup>

#### **21.3.4 Internal consistency**

Another aspect of the quiz to consider is its 'internal consistency', a measure that assesses the consistency across the different questions in the quiz.<sup>620</sup> It is important to evaluate if the quiz questions are testing a similar aspect of knowledge.<sup>618</sup> One of the methods for assessing internal consistency is Cronbach's alpha.<sup>620</sup> Cronbach's alpha is recognised as providing a measure of how well each individual question correlates with the sum of all the remaining questions.<sup>618</sup> If all the questions are identical to each other the Cronbach's alpha score will equal 1. If all the questions are independent the Cronbach's alpha score will be zero.<sup>621</sup> Ideally, the Cronbach's alpha score should be greater than 0.7. but no greater than 0.9.<sup>620</sup> A low value of alpha could be due to a low number of questions or poor interrelatedness between items. A score higher than 0.9 suggests that some questions are repetitive so may be redundant.<sup>620</sup> To test the internal consistency of the RedUSE OAMHP quiz each of the pilot participant group scores was tested, as were the combined question scores of all participant groups.

#### **21.4 Statistical analysis**

The statistical analyses were performed using StatView, v 5.0 (SAS Institute Inc., Cary, NC) and SPSS version 18 (IBM, Chicago, IL). OAMHP quiz scores were calculated for each participant as the percentage of correct responses. A one-way between-groups analysis of variance (ANOVA) test was used to compare the differences in mean scores of subjects between accredited/academic pharmacists, third year pharmacy students and first year pharmacy students. All tests were two-sided and  $p$ -values  $< 0.05$  were considered statistically significant. Spearman's Rank coefficient was used for the test-retest reliability analysis. Cronbach's alpha coefficient values were calculated to test the internal consistency of the quiz.

#### **21.5 Results**

A total of 14 accredited pharmacists/pharmacy academics, 27 third year pharmacy students and 25 first year pharmacy students completed the pilot OAMHP quiz. Fifteen of the third year students were re-tested with the quiz 64 days after initial administration.

### 21.5.1 Construct validity

The Mean scores for each group are listed in Table 55 below:

<b>Table 55: OAMHP quiz scores</b>			
Variable	Accredited pharmacists/pharmacy academics N = 14	Third year pharmacy students N = 27	First year pharmacy students N = 25
Scores (mean (S.D))	8.43 (1.22)	6.04 (1.61)	3.12 (1.62)

A one-way between-groups analysis of variance was conducted to evaluate the difference in OAMHP scores between the accredited/ academic pharmacists, and the third and first year pharmacy students. There was a statistically significant difference in quiz scores for the three groups:  $F(2, 66) = 18.5, P < 0.0001$ . Post-hoc comparisons using the Fisher's PSLD test indicated that the mean score for the accredited/academic pharmacists ( $M = 8.43, SD = 1.22$ ) was significantly different from both the third year student pharmacist group ( $M = 6.04, SD = 1.61$ , mean difference = 2.4,  $P < 0.02$ ) and the first year student pharmacist group ( $M = 3.12, SD = 1.62$ , mean difference = 5.3,  $P < 0.0001$ ). Likewise, the two student pharmacist group OAMHP scores were significantly different from each other; (mean difference = 2.9,  $P < 0.005$ ). Thus, the mean score for participants between the three groups was significantly different, supporting construct validity.

### 21.5.2 Test-Retest Reliability

The test-retest results of the subset of third year pharmacy students ( $n = 15$ ) are shown in Table 56 as follows:

<b>Table 56: OAMHP test-retest quiz scores</b>		
Variable	Third year pharmacy students Baseline (t = 0) N = 15	Third year pharmacy students T = 64 days N = 15
Scores (mean (S.D))	5.93 (1.22)	6.13 (1.06)

These students were retested 64 days after initial quizzing. The difference in the two mean scores was 0.2 marks. When the scores for each student for the initial quiz and retest were tested with Wilcoxon Signed rank test, there was no significant difference: ( $Z = -0.11, P = 0.92$ ). When a Spearman Rank correlation coefficient was calculated between the two quiz scores from each administration it was found to be 0.87. A coefficient of 0.8 or higher is considered acceptable for demonstrating re-test reliability.<sup>616</sup>



### 21.5.3 Internal consistency

The quiz scores of the pilot groups were analysed for internal consistency using Cronbach's alpha (Table 57).

**Table 57: OAMHP internal consistency scores**

Pilot participant group	Mean (SD)	Number	Cronbach's Alpha
Accredited pharmacists/ pharmacy academics	8.43 (1.22)	14	0.33
Third year pharmacy students	6.04 (1.61)	27	0.27
First year students	3.12 (1.62)	25	0.16
Total participants	5.85 (2.89)	66	0.70

The scores of internal consistency in each separate sample group using the Cronbach's alpha test were 0.33, 0.27 and 0.16, very low coefficients for internal consistency. This means that the questions were not interrelated to each other in the individual groups. However, when the Cronbach's alpha score was calculated for the combined participants ( $n = 66$ ), the Cronbach's alpha score was 0.7 which is considered acceptable to show a fair degree of internal consistency in question results.<sup>620</sup> Only the removal of question three, the question related to the side effects of olanzapine, would have improved the Cronbach's score, from 0.70 to 0.71.

## 21.6 Discussion

Several questions of the first draft OAMHP quiz were amended on the advice of several medical specialists and educational experts. Further, when the quiz was shown to the small group of nurses at a RACF, a few small amendments were made. When the revised quiz (Figure 17) was shown to the same group of nurses, the quiz was deemed acceptable for the population studied. This fact was reflected in the finding that the completion rate of the quiz was 98% among the 72 participants that piloted the study. The nurses also commented that the quiz only took a few minutes to complete.

By using the 'contrasted groups' method, test-retest assessments and internal consistency reliability analysis it was aimed to assess the ability of the quiz to identify deficits in the nursing staff knowledge. Another aim of the quiz was to detect improvements in psychotropic medication knowledge after two educational sessions were provided. It was found that the OAMHP test was able to distinguish between the knowledge of different groups of participants and that the reliability of the test stood up to the challenge when tested 2 months later in the same group of students. The internal consistency using the Cronbach's alpha test was acceptable

when all the total of the quiz results were combined, showing that the questions were measuring the same aspect of knowledge.

In retrospect, it was suspected that many of the participants piloting the OAMHP quiz guessed some of the answers. Other researchers have suggested that the internal consistency of knowledge instruments is often improved if a 'don't know' option is included as an answer option. For instance, when students at a large university in New Zealand were administered a questionnaire on ageing in a 'True-False' format, or with a 'Don't Know' option added, the authors found that the addition of a 'Don't Know' option decreased the percentages of correct answers, as well as errors, and suggested that this version provides a more accurate picture of knowledge by reducing guessing.<sup>622</sup> The version of the questionnaire with the 'Don't-Know' option had a significantly higher internal consistency.<sup>622</sup> If future 'knowledge-based' quizzes are to be developed, the addition of a 'Don't Know' option would be an advisable option to improve the internal consistency of the knowledge instrument.

### **21.7 Strengths and limitations**

As there were no existing old age mental health psychotropic tests, one was purpose designed for the RedUSE trial. The OAMHP quiz was found to be a valid and reliable instrument and suitable for assessing background knowledge and for measuring changes in knowledge. The validation process of the quiz was found to have some limitations, however. One limitation of our testing procedure was that we used groups of pharmacists and pharmacy students to test the quiz instead of nursing staff for whom the test was designed for. The reason for this was that it was very difficult to find sufficient numbers of RACF nursing staff to sample. As there was already significant administration associated with the RedUSE trial itself, the researchers were conscious of not overloading the RACF nursing staff with additional tasks. For this reason, it was decided to test the quiz on pharmacists/pharmacy students instead. It should be noted by the time the students had attained third year, the success rate of two of the quiz questions was 100%. Although these questions were easy for pharmacists to answer, they were left in the quiz because an assumption was made that nursing staff would not have as extensive pharmacological knowledge as pharmacists.

### **21.8 Conclusion**

The RedUSE OAMHP quiz is a valid and reliable instrument that has been reviewed, piloted and evaluated statistically to identify faults in its format and content. Through piloting and testing, this quiz was deemed suitable to determine a nurse's psychotropic knowledge deficits and measure changes in knowledge over time.

## CHAPTER TWENTY TWO: RESULTS

### AN INTERVENTION TO IMPROVE QUALITY PSYCHOTROPIC USE IN RACFS

#### **22.1 Baseline data collection**

##### **22.1.1 The intervention and control RACF and pharmacy sample**

Out of 27 RACFs in Hobart approached to participate in RedUSE, 18 facilities expressed interest in participating. Four facilities were excluded as they had multiple community pharmacies supplying medications or they were not using a computerised medication packing system. One RACF was not able to participate as their community pharmacy declined to be involved. This pharmacy said had recently covered benzodiazepine use in their RACF and did not want to 'upset' their GPs by reconsidering the topic. Although the study power calculation called for 12 facilities in each group, a group of 5 RACFs part of the same religious ownership requested to join the intervention arm of the trial after 8 facilities had already signed on. As the central RACF management specifically requested that all their Hobart facilities be involved, the additional facility was allowed to participate. It should be noted that all these RACFs were managed independently and situated in different areas of Hobart. This led to a total of thirteen RACFs in the intervention arm of the trial. All but one of the community pharmacies approached in the intervention arm agreed to participate in the RedUSE trial, giving a total of 8 participant pharmacies.

Out of 19 RACFs in Launceston approached to participate in the RedUSE trial, 13 facilities expressed interest in participating. However, one of the facilities switched supply community pharmacies just before the trial started, meaning dispensing data was inaccessible, and they were not eligible. All 7 pharmacies supplying control RACFs agreed to participate.

The RedUSE psychotropic audit program was installed at all fifteen pharmacies in the trial. In total, 75 psychotropic audit measures were obtained from all 25 RACFs, one at baseline, and the other two at 3 and 6 month intervals. At one of the control pharmacies difficulty was experienced installing the RedUSE program. This meant that the final psychotropic audit measure had to be manually entered into a laptop computer at the RACF itself and then entered into the RedUSE psychotropic audit program separately.

##### **22.1.2 Facility characteristics**

The average total number of residents in the 13 intervention and 12 control RACFs over the three data collection periods was 898 and 693 residents, in each group, respectively; resulting in an average total of 1 591 residents per measure (range 1575-1605). There were no statistically significant differences between control and intervention characteristics at baseline (Table 58).

**Table 58: Baseline characteristics of participating RACFs**

<b>RACF CHARACTERISTIC</b>	<b>INTERVENTION AGED HOMES (n = 13)</b>	<b>CONTROL AGED HOMES (n = 12)</b>	<b>TEST FOR SIGNIFICANT DIFFERENCES*</b>
Mean size (range) (number of beds)	69.1 (34-116)	57.3 (19-96)	$t(23) = 1.2$ , $p = 0.3$ (two-tailed)
Mean proportion of high-care residents	73.52	76.97	$t(23) = -0.4$ , $p = 0.7$ (two-tailed)
Proportion (number) of rural RACFs	23.1 (3)	33.3 (4)	$p = 0.7$ Fishers exact test
Mean proportion residents on psychotropics	61.1	62.4	$t(23) = -0.3$ , $p = 0.6$ (two-tailed)
Mean proportion of residents taking 2+ psychotropics	29.0	27.4	$t(23) = 0.5$ , $p = 0.9$ (two-tailed)
Mean proportion of residents taking 3+ psychotropics	8.2	6.2	$t(23) = 1.5$ , $p = 0.5$ (two-tailed)
Mean proportion of residents taking antipsychotics	20.3	21.9	$t(23) = 0.5$ , $p = 0.4$ (two-tailed)
Mean proportion of residents taking benzodiazepines	31.9	30.4	$t(23) = 0.4$ , $p = 0.5$ (two-tailed)
Mean proportion of residents taking antidepressants	39.5	37.3	$t(23) = 0.6$ , $p = 0.3$ (two-tailed)
Mean Chlorpromazine Equivalence Dose (mg)	20.9	24.9	$t(23) = -0.8$ , $p = 0.4$ (two-tailed)
Mean Diazepam Equivalence Dose (mg)	3.7	2.9	$t(23) = 1.7$ , $p = 0.1$ (two-tailed)

\*None of the differences were statistically significant ( $p < 0.05$ )

Each of the 15 community pharmacies supplying the twenty-five participant RACFs were asked to provide details about their RMMR program, the number of medication review services performed before and during the RedUSE trial, and associated QUM service provision. These details are summarised in Table 59 for both intervention and control RACFs.

All participant RACFs had a RMMR agreement in place throughout 2008 and all facilities received RMMR services during 2008. Four RACFs in the intervention group and 3 facilities in the control group did not have RMMR services performed in the 6 months prior to the RedUSE project. In the latter half of 2008, all of the RACFs except two control facilities received RMMR services. These two control facilities were unable to find a pharmacist to conduct RMMRs in the latter half of 2008. When the ratios of RMMRs performed per facility,

per resident during 2008 were compared between the intervention and control groups, the two groups were found to be almost identical, with the calculated ratio of 0.862 in intervention RACFs and 0.864 in control RACFs. It can be seen, however, that a greater proportion of RMMR services were undertaken in the first half of 2008 in the control facilities (23% of RMMR services were conducted prior to the RedUSe project as compared to 14% of RMMR services conducted in the first half of 2008 in intervention facilities). However, this difference was not significant when tested with a Chi-squared test (23% vs. 14%,  $\chi^2 = 2.1$ , (df=1)  $p = 0.15$ ).

#### *22.1.2.2 Existing QUM services supplied by participant RACFs*

The provision of QUM services was also compared between the intervention and control groups. A total of 62% of the intervention RACFs received QUM services (aside from RedUSe) in 2008, contrasting with a figure of 83% of control RACFs (see Table 59). For those 18 RACFs receiving services, all reported QUM activity included educational sessions for nursing staff. Most of the community pharmacies said that their educational sessions were, on the whole, unstructured talks by one of their pharmacists, although one control pharmacy had presented the PSA 'dementia' kit to their two RACFs.<sup>609</sup>

A consultant group of accredited pharmacists had prepared and delivered educational sessions at four of the intervention facilities and two of the control facilities. Four of the intervention RACFs (36%) and six of the control facilities (50%) were represented by their pharmacy at Medication Advisory Committees. Of note is the finding that only two medication audits were conducted in two of the control facilities throughout the entire 25 RACF sample.

**Table 59 RedUSE RACF data: no. of residents, RMMR and QUM services provided**

<b>Inter- vention RACF no</b>	<b>Average number residents (8/08- 3/09)</b>	<b>RMMR service agreement 2008 ?</b>	<b>No of RMMR services conducted Jan-Jul 2008</b>	<b>No of RMMR services conducted Aug08- Feb09</b>	<b>QUM services provided during 2008 (except RedUSE)</b>	<b>QUM services by accredited pharmacist ?</b>
<b>1</b>	34	yes	8	3	nil	Yes
<b>2</b>	54.7	yes	19	47	1 talk	Yes
<b>3</b>	91	yes	3	102	4 education sessions, MAC	Yes
<b>4</b>	100.7	yes	2	106	2 talks at MAC	No
<b>5</b>	96	yes	13	95	2 talks at MAC	No
<b>6</b>	55	yes	22	51	1 talk	Yes
<b>7</b>	112.3	yes	26	18	nil	No
<b>8</b>	89	yes	3	106	4 educational sessions, MAC	Yes
<b>9</b>	70	yes	0	19	4 educational sessions	Yes
<b>10</b>	79	yes	0	63	nil	No
<b>11</b>	44.7	yes	0	40	nil	No
<b>12</b>	36	yes	0	17	4 educational sessions	Yes
<b>13</b>	35.7	yes	9	2	Nil	Yes
<b>average</b>	<b>69.1/RACF</b>		<b>105 (8.1/RACF)</b>	<b>669 (51.6/RACF)</b>		
<b>Contr ol RACF no</b>	<b>average number residents ( 8/08- 3/09)</b>	<b>RMMR service agreement 08?</b>	<b>No of RMMR services conducted Jan-Jul 08</b>	<b>No of RMMR services conducted 8/08-Feb09</b>	<b>QUM services provided 2008 (except RedUSE)</b>	<b>QUM services by accredited pharmacist ?</b>
<b>14</b>	46.7	yes	22	30	2 talks, MAC NPS DUE	Yes
<b>15</b>	93.3	yes	11	91	2 educational sessions, MAC	Yes
<b>16</b>	76.3	yes	14	82	3 talks + MAC	No
<b>17</b>	66.0	yes	34	38	2 educational sessions, audit	Yes
<b>18</b>	19.3	yes	0	21	2 educational sessions	No
<b>19</b>	62.0	yes	5	71	1 talk + MAC	No
<b>20</b>	78.3	yes	2	47	1 talk + MAC	No
<b>21</b>	73.7	yes	25	0	nil	Yes
<b>22</b>	63.7	yes	4	65	2 educational sessions, MAC	Yes
<b>23</b>	39.7	yes	0	8	2 QUM sessions	Yes
<b>24</b>	33.3	yes	0	5	2QUM sessions	Yes
<b>25</b>	35.7	yes	19	0	nil	Yes
<b>average</b>	<b>57.3/RACF</b>		<b>136 (11.3/RACF)</b>	<b>458 (38.2/RACF)</b>		

## **22.2 Training Evaluation**

### **22.2.1 Evaluation of Pharmacist Training Weekend**

Evaluation reports were submitted by eight of the ten pharmacists attending the RedUSE training weekend which was held at the beginning of July 2008. The evaluation form consisted of eight questions, with a final rating allocated to the entire training event. The evaluation was anonymous and completed after the final educational session on the Sunday. Table 60 summarises the reports.

**Table 60: Evaluation report summary of RedUSE Pharmacist training**

<b>Questions</b>	<b>Responses</b>
<i>1. Did the training increase your understanding of the Quality use of psychotropic medication in older people?</i>	All eight pharmacists answered 'yes'. One commented, 'a very good refresher'
<i>2. Has the training influenced your attitude / perception of how you can promote the appropriate use of sedatives in aged care?</i>	All eight pharmacists answered 'yes'. Two of the pharmacists felt that the training 'has given me more confidence.'
<i>3. Which activities or training methods did you find the most effective in conveying the course content?</i>	Five of the participants ranked the case studies, and two ranked the panel discussion as the most effective training methods. One of the pharmacists elaborated further; "good to hear from GPs and nursing staff"- very valuable.'
<i>4. What would you like to see included or covered in greater depth in the training?</i>	Three of the participants did not answer and one commented that they thought the content just right. Of the other four respondents, one pharmacist wanted more clinical information and another requested more case studies. The other two pharmacists wanted more ideas about coping with resistance to change and non-drug strategies.
<i>5. Do you feel equipped to provide the strategies of RedUSE as a QUM activity in the aged care homes you service?</i>	Seven of the pharmacists felt that they were equipped and the final pharmacist thought they were 'nearly' equipped. Several of the Pharmacists were pleased that a researcher would help them install and run the program initially.
<i>6. Your rating of the overall effectiveness of the training? 1. Excellent 2. Very good 3. Good 4. Fair 5. Poor .</i>	Three pharmacists ranked the training as excellent and five ranked the training as very good.
<i>7. Your comments on the pace of the course and the level of challenge/difficulty?</i>	All the pharmacists thought the training was well paced and aimed at the right level. One of the pharmacists thought this aspect of the training was excellent. One of

8. Your comments about any other aspects of the RedUSE training. e.g. catering, timing of course, remuneration.

the pharmacists commented; “as always there is never enough time! Less for training and maybe more practiced discussions with the two health professionals.”

Four of the pharmacists did not add any further comments. Two pharmacists added that they felt it was all good. One final comment:: “All above aspects of the course were positive. I look forward to being involved.”

### 22.2.2 Evaluation of RedUSE launch

The RedUSE launch event was attended by 91 health professionals including GPs, nursing staff and pharmacists. Anonymous evaluation forms were placed in front of each place setting before attendees arrived. Each participant completed the same form regardless of profession and details were not sought regarding professional training. Participants were asked to rank certain aspects of the project on an analogue scale. A total of 26 forms were completed giving a participation rate of 29%. The feedback from the evaluation is summarised below in Table 61.

**Table 61: Evaluation report summary of RedUSE launch presentation**

<b>Evaluation for RedUSE Launch 28Aug08</b>	<b>Mean Ranking: ...../ 5</b>	<b>Standard Deviation</b>	<b>comments</b>
Presentation	4.5	0.5	Very relevant and useful.
Content	4.4	0.5	Excellent presentation, wonderful research, good idea to have resources of NSW
Question time	3.9	0.8	Invite Minister of Health
Relevance to practice	4.5	0.7	It did allow people to gain an insight into the roles others can play
Re-enforced knowledge	4.3	0.9	The session was very informative
Changed attitudes towards prescribing of sedatives	3.8	1.0	I look forward to this project and reducing the use of meds

### 22.2.3 Evaluation of the nurse educational sessions

Two nursing staff training sessions were held, one after the baseline and one after the 3-month psychotropic audit measurements in each of the 13 intervention RACFs. All education was delivered by 8 community pharmacists who had attended the pharmacist RedUSE training. A total of 105 RACF nursing staff from intervention facilities attended the first educational session (55 RNs, 47 ENs and 3 PCAs), and 71 nursing staff attended the second session (44 RNs, 26 ENs and 1 PCA). Fifty of the nursing staff attending the first session also attended the follow-up session (27 RNs and 23 ENs).



All RACF nursing staff members attending an educational session were asked to complete an anonymous evaluation form at the end of the each session. The evaluation form



asked participants to rank four aspects of the presentation using a visual analogue score from 1 to 5 where “1” was ranked as ‘unsatisfactory’ and “5” as ‘very satisfactory’. The nursing staff were also asked to rank whether their knowledge was enhanced, and attitudes around sedative use altered, as a result of the session. A section was also included for staff comments. A sample evaluation form is shown as Figure 18.

Eighty-five nursing staff members (81% of participants) completed an evaluation form for the first training session and 69 nursing staff (97% of participants) completed an evaluation report for the second training session. Overall, the training was ranked very highly with all aspects of the training being ranked more than 4 marks out of a possible 5 marks in all six questions. The Mean mark allocated to each question, its standard deviation (SD) and further comments made by nursing staff participants are all shown in Table 62.

**Figure 18: Nursing evaluation form for RedUSE Nurse Educational Sessions**

**Evaluation for nursing staff education:**  
**August / September 2008**

**On a scale of 1 to 5 (1 being unsatisfactory and 5 being very satisfactory) please rate your level of satisfaction with the following aspects of the session:**

<b>Presentation:</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>Content:</b>	1	2	3	4	5
<b>Discussion time:</b>	1	2	3	4	5
<b>Relevance to your Practice:</b>	1	2	3	4	5

**The educational session has reinforced my knowledge about the use of sedative drugs for residents of RACFs.**

Not at all	1	2	3	4	5	Greatly
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**My attitudes around the prescribing of sedative medication in RACFs have altered as a result of this educational session.**

Not at all	1	2	3	4	5	Greatly
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**Please add any further comments about the training or suggestions on how it could be improved:**

.....

**Table 62: Evaluation report summary of RedUSE Nursing staff educational sessions**

<b>First training Aug/Sept 08</b>	Mean Ranking: ...../ 5	Standard Deviation	comments
Presentation	4.6	0.6	Good presentation.
Content	4.7	0.5	Learnt things I didn't know about sedatives
Discussion time	4.4	0.7	As a new nurse I found this great but would like a handout so I can study further
Relevance to practice	4.9	0.4	Older GPs tend to prescribe more. Younger GPs open to discussion with staff.
Re-enforced knowledge	4.7	0.7	The session was very informative
Changed attitudes towards sedatives	4.2	1.1	I have never believed in medicating people to deal with Behaviours
<b>Second educational session Dec08/Jan09</b>			
Presentation	4.6	0.7	Could we have a case study of a specific resident
Content	4.6	0.7	I would appreciate regular pharmacology sessions
Discussion time	4.3	0.9	More than willing to answer any questions asked
Relevance to practice	4.7	0.7	We are committed to use these medications with awareness. To review regularly with GP
Re-enforced knowledge	4.6	0.6	Educational - great!
Changed attitudes towards sedatives	4.3	1.0	I have always been concerned about overuse of sedatives

The pharmacists delivering the RedUSE educational sessions in the intervention RACFs also evaluated the nurse educational sessions as the 'trainer'. The sessions were evaluated by the same method as the nursing staff except that half of the questions differed slightly and sought to gauge the pharmacists' opinion of the acceptability of the nurses training package and the level at which the presentation was pitched. All eight of the pharmacists conducting educational sessions completed an evaluation form. A summary of the evaluation is presented as Table 63.

### **22.3 Effectiveness of nursing staff educational sessions**

At the beginning of the staff educational session, all of the nursing staff attendees were asked to complete the OAMHP quiz which was devised and validated to assess knowledge on old age mental health psychotropic medications. The average quiz score of the RNs was 64.4% (SD 19.5%), and the average quiz score of the ENs was 50.2% (SD 16.6%). The results of the first quiz are shown in Table 64 overleaf.

**Table 63: Pharmacist Evaluation report summary of RedUse Nursing presentation**

<b>Evaluation for RedUse training – first session</b>	Mean Ranking: ...../ 5	Standard Deviation	Comments
Presentation	4.9	0.3	An excellent resource, informative, attractively presented and very easy to use.
Content	4.4	0.5	Nurses want handouts, brief overview of projects important points
Discussion time	4.0	1.3	Makes drug discussions with staff very manageable & productive
Nursing acceptance	4.8	0.5	Cast nurse in stronger role in case study
Pitched at right level	4.3	0.4	Quiz, some found some of the questions ambiguous.
Difficult to deliver?	1.5	1.1	Simplify names of benzos, add a list of benzos.

When the results of the baseline RedUse psychotropic quiz were examined in detail, it was noted that some questions were more likely to be answered incorrectly than others. In particular, those questions related to the side effects of psychotropic medication or the duration of treatment were answered poorly. For example, many of the nurses were unaware that hyperglycaemia was a side effect of olanzapine, or that memory impairment was a common side effect of benzodiazepine use. The majority of nursing staff, particularly ENs, were unaware of the recommended duration of benzodiazepine and antipsychotic use. Less than half of the registered and enrolled nurses knew that the recommended duration of benzodiazepine use was 2-4 weeks. One finding of particular concern was that the majority of ENs (60%) and over a third of RNs (36%) thought that oxazepam, a very commonly prescribed anxiolytic benzodiazepine, was prescribed as an antipsychotic or as an antidepressant agent.

**Table 64: OAMHP baseline quiz scores for nursing staff**

<b>OAMHP Question</b>		<b>RN Correct Score (%)</b>	<b>EN Correct Score (%)</b>
1	Risperidone is most effective for the treatment of which behaviour?	90	79
2	The maximum recommended daily dose of risperidone is:	38	40
3	which of the following side effects has not been associated with olanzapine?	35	25
4	Regular trials of reducing antipsychotic doses should be performed every:	58	70
5	The drug diazepam is indicated to treat:	98	72
6	Which of the following side effects is not associated with benzodiazepine use?	75	49
7	What is the recommended duration of benzodiazepine treatment?	48	47
8	The first-line medication treatment for depression in older people is:	67	49
9	Tricyclic antidepressants are recommended as a night time sedative.	67	52
10	Oxazepam belongs in which psychotropic drug group?	58	31

In order to assess the effectiveness of the RedUSE staff training educational sessions, the same quiz was repeated at the end of the second staff training session. Quiz results for those nursing staff that completed the quiz before and after the educational sessions are shown in Table 65.

**Table 65: Mean Quiz scores for registered and enrolled nurses before the first staff training session and after the second staff training session**

	Pre-training Mean score %	Post-training Mean Score %	Difference %
Registered Nurses (N = 26)	69.6	87.3	17.7
Enrolled Nurses (N = 21)	49.0	76.7	27.7

The mean quiz scores for both ENs and RNs improved after attending the two RedUSE training sessions, with a greater score improvement seen in the EN scores. When the pre and post training scores were tested with a paired t-test, a significant increase in the mean quiz score was found in both the RN and EN groups: For RNs; pre-training score ( $M = 69.6$ ,  $SD = 16.4$ ) to post-training score ( $M = 87.3$ ,  $SD = 12.5$ ),  $t(25) = 4.0$ ,  $p = 0.0005$  (two-tailed). For ENs the improvement was more pronounced; pre-training score ( $M = 49.0$ ,  $SD = 18.4$ ) to post-training score ( $M = 76.7$ ,  $SD = 18.0$ ),  $t(20) = 6.8$ ,  $p < 0.0001$  (two-tailed).

## **22.4 Psychotropic prevalence**

### **22.4.1 Rates of Antipsychotic and Benzodiazepine use**

The antipsychotic and benzodiazepine prevalence rates of the individual intervention RACFs are listed in Table 66 and the prevalence rates of the control RACFs are listed in Table 67. Both antipsychotic and benzodiazepine prevalence rates decreased in the intervention facilities over the trial period, whereas the prevalence rates of both agents increased in control facilities.

Nine out of the 13 intervention RACFs (70%) reported a decrease in antipsychotic use over the 6 month trial, and over three quarters of intervention facilities (77%) reported a reduction in benzodiazepine use. In contrast, only two of the control RACFs (16%) recorded a reduction in antipsychotic use, and only a quarter (25%) of control facilities recorded a decrease in benzodiazepine prevalence.

**Table 66: Intervention RACF size, antipsychotic and benzodiazepine prevalence at baseline (wk 0), week 12 and week 26**

Home code	no. of residents			average no. residents	antipsychotic rate			benzodiazepine rate		
	Wk 0	Wk 12	Wk 26		Wk 0	Wk 12	Wk 26	Wk 0	Wk 12	Wk 26
1	34	34	34	34	5.9%	2.9%	0.0%	23.5%	17.6%	14.7%
2	55	55	54	54.7	27.3%	25.5%	25.9%	47.3%	36.4%	37.0%
3	92	94	87	91	16.3%	16.0%	14.9%	30.4%	25.5%	24.1%
4	98	104	100	100.7	22.4%	18.3%	23.0%	31.6%	25.0%	29.0%
5	100	97	91	96	22.0%	21.6%	22.0%	34.0%	28.9%	30.8%
6	56	55	54	55	30.4%	27.3%	29.6%	35.7%	45.5%	38.9%
7	106	116	115	112.3	30.2%	26.7%	27.0%	26.4%	25.0%	20.0%
8	93	88	86	89	15.1%	19.3%	16.3%	38.7%	34.1%	32.6%
9	70	70	70	70	15.7%	14.3%	12.9%	45.7%	38.6%	32.9%
10	78	79	80	79	15.4%	13.9%	13.8%	25.6%	27.8%	26.3%
11	44	45	45	44.7	29.5%	22.2%	24.4%	29.5%	28.9%	31.1%
12	29	40	39	36	27.6%	20.0%	23.1%	27.6%	25.0%	23.1%
13	36	38	33	35.7	5.6%	7.9%	9.1%	16.7%	13.2%	9.1%
Total % of residents				69.1	20.3%	18.1%	18.6%	31.8%	28.6%	26.9%

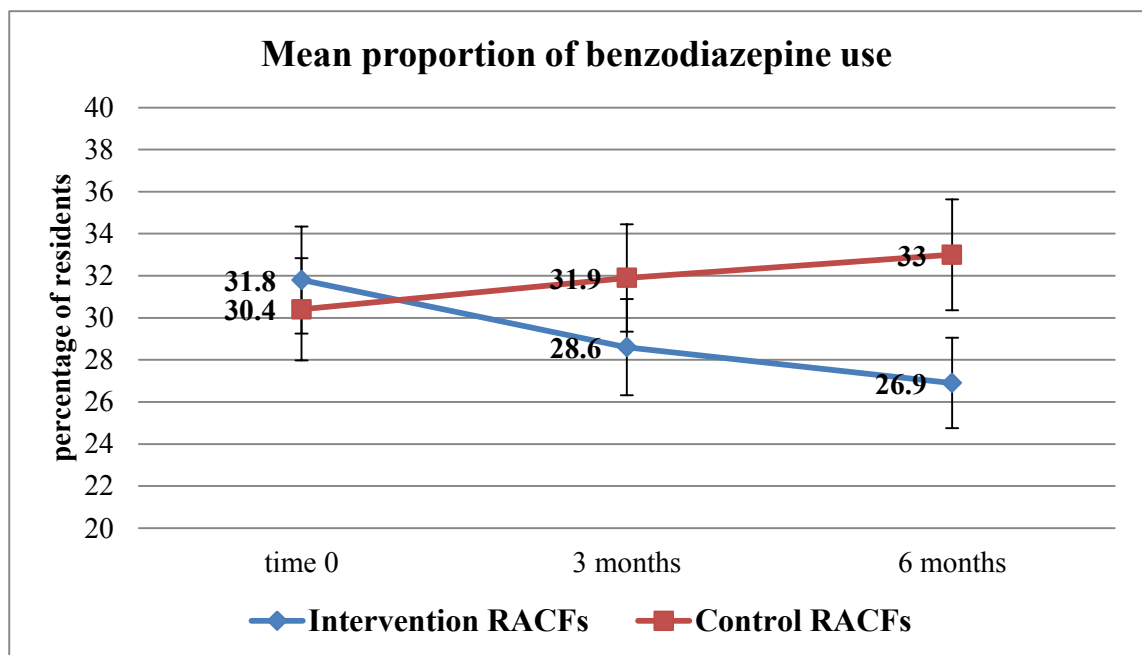
**Table 67: Control RACF size, antipsychotic and benzodiazepine prevalence at baseline (wk 0), week 12 and week 26**

Home code	no. of residents			average no. residents	antipsychotic rate			benzodiazepine rate		
	wk 0	Wk 12	Wk 26		wk0	wk12	wk26	wk0	wk12	wk26
14	48	46	46	46.7	25.0%	30.4%	32.7%	14.6%	19.6%	26.5%
15	96	92	92	93.3	27.1%	29.3%	28.3%	26.0%	28.3%	23.9%
16	75	77	77	76.3	9.3%	10.4%	12.0%	41.3%	35.1%	32.5%
17	68	65	65	66.0	17.6%	16.9%	18.2%	29.4%	32.3%	36.4%
18	20	19	19	19.3	20.0%	21.1%	26.3%	25.0%	36.8%	36.8%
19	64	61	61	62.0	21.9%	16.4%	15.6%	32.8%	32.8%	31.3%
20	77	79	79	78.3	27.3%	29.1%	27.3%	22.1%	22.8%	29.9%
21	71	75	75	73.7	29.6%	28.0%	21.4%	38.0%	37.3%	38.6%
22	63	64	64	63.7	20.6%	20.3%	25.0%	33.3%	34.4%	34.4%
23	37	41	41	39.7	24.3%	26.8%	33.3%	45.9%	43.9%	48.9%
24	32	34	34	33.3	6.3%	5.9%	7.5%	37.5%	32.4%	37.5%
25	33	37	37	35.7	33.3%	29.7%	38.9%	18.2%	27.0%	19.4%
Total % of residents				57.3	21.9%	22.0%	23.9%	30.4%	31.9%	33.0%

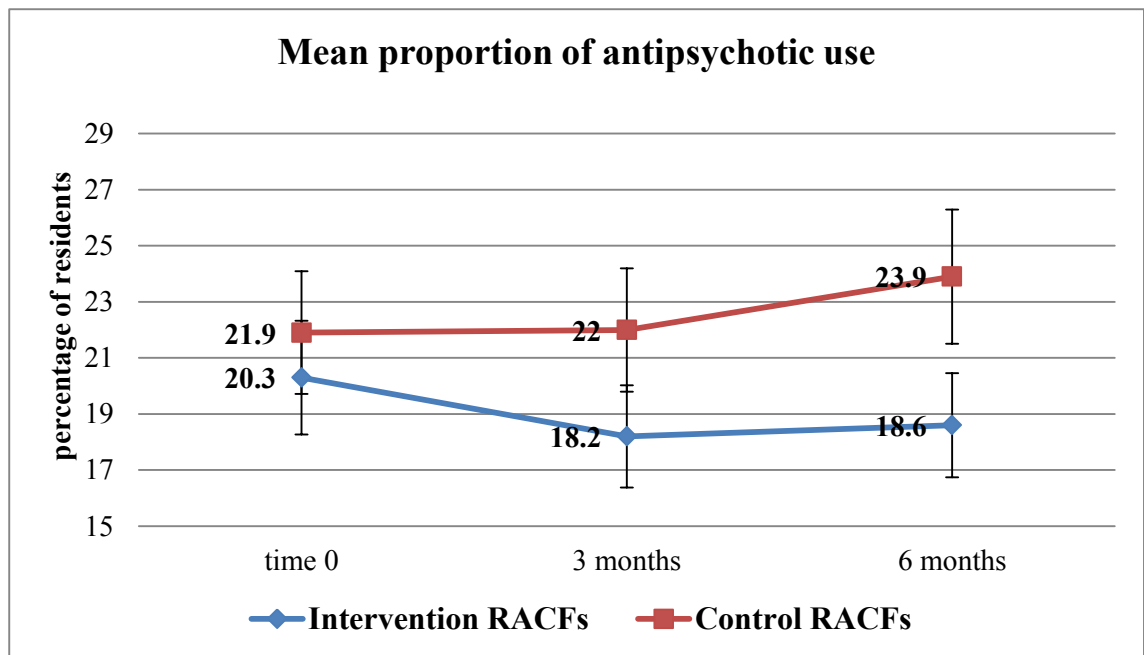
When students' two way t-tests were applied to the RACF prevalence data, there was a statistically significant decrease in the mean proportion of benzodiazepines used in intervention RACFs from baseline (Mean ( $M$ ) = 31.8% residents, Standard Deviation ( $SD$ ) = 8.6) to time 26 weeks ( $M$  = 26.9% residents,  $SD$  = 8.6),  $t$  (12) = 3.7,  $p$  < 0.005 (two-tailed). The decrease in the mean proportion of antipsychotic use in intervention RACFs from baseline ( $M$  = 20.3% residents,  $SD$  = 8.7) to time 26 weeks ( $M$  = 18.6% residents,  $SD$  = 8.4), was also significant:  $t$  (12) = 2.2,  $p$  < 0.05 (two-tailed). Results of the 2-way, repeated measures ANOVA for the intervention group RACF data showed a statistically significant effect of the intervention on benzodiazepine use ( $p$  < 0.001) and also on antipsychotic use ( $p$  < 0.05).

The changes in the mean proportion of residents taking antipsychotic and benzodiazepine therapy in intervention and control RACFs are shown graphically over time at Figure 19 and Figure 20. N.B. The error bars on the bar graphs in the results pages represent the confidence intervals (CIs) for each mean.

**Figure 19: Mean proportion of benzodiazepine use in intervention vs. control RACFs**



**Figure 20: Mean proportion of antipsychotic use in intervention vs. control RACFs**

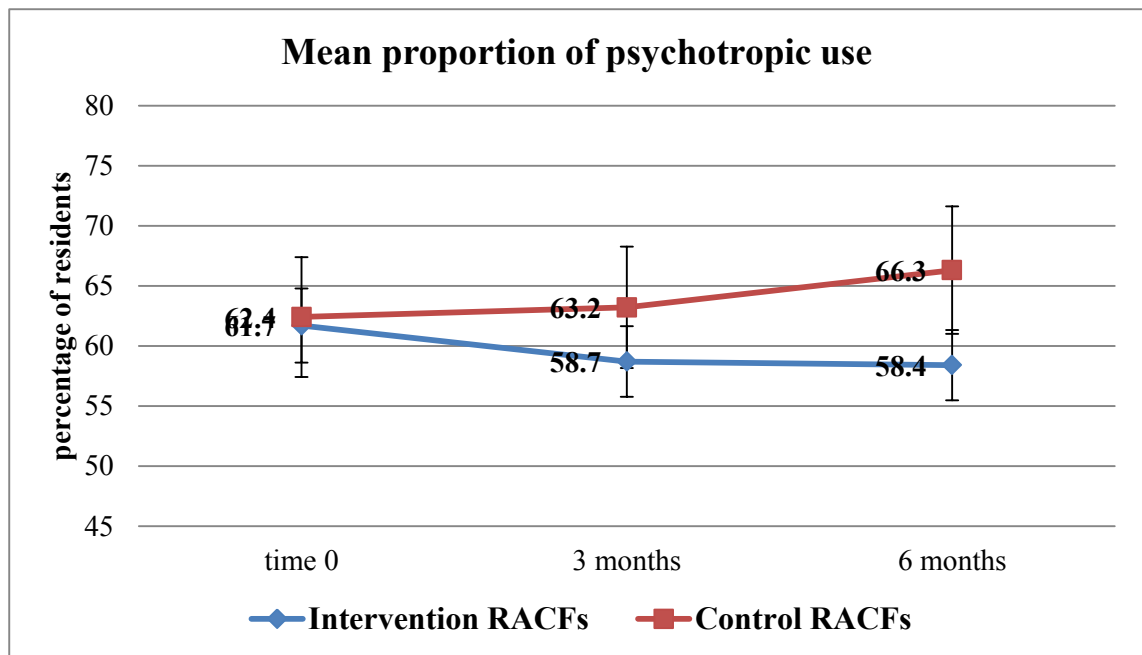


There were no statistically significant differences in either benzodiazepine or antipsychotic prevalence rates in the control RACFs during the trial; Baseline mean ( $M$ ) benzodiazepine use: ( $M = 30.4\%$  residents,  $SD = 9.6$ ) to time 26 ( $M = 33.0\%$  residents,  $SD = 7.7$ ),  $t(11) = -1.5$ ,  $p = 0.2$  (two-tailed); baseline mean antipsychotic use: ( $M = 21.9\%$  residents,  $SD = 7.9$ ) to time 26 weeks ( $M = 23.9\%$  residents,  $SD = 9.3$ ),  $t(11) = -1.3$ ,  $p = 0.2$  (two-tailed).

#### **22.4.2 Rates of overall psychotropic use**

The overall psychotropic agent use decreased in the intervention RACFs, whereas this value increased in control RACFs over the trial period. These results are shown in Figure 21. There was a statistically significant decrease in overall psychotropic agent use in intervention RACFs from baseline ( $M = 61.1\%$  residents,  $SD = 11.9$ ) to time 26 weeks ( $M = 58.4\%$  residents,  $SD = 12.3$ ),  $t(12) = 2.4$ ,  $p < 0.05$  (two-tailed). A 2-way R-ANOVA test confirmed a statistically significant effect of the intervention on overall psychotropic use ( $p < 0.005$ ). However, in control RACFs the overall use of psychotropic agents increased; albeit non-significantly. Mean psychotropic use: baseline  $M = 62.4\%$  residents,  $SD = 9.2$ ) to time 26 weeks ( $M = 66.3\%$  residents,  $SD = 10.8$ ),  $t(11) = -1.8$ ,  $p = 0.09$  (two-tailed);

**Figure 21: Mean proportion of psychotropic use in intervention vs. control RACFs**



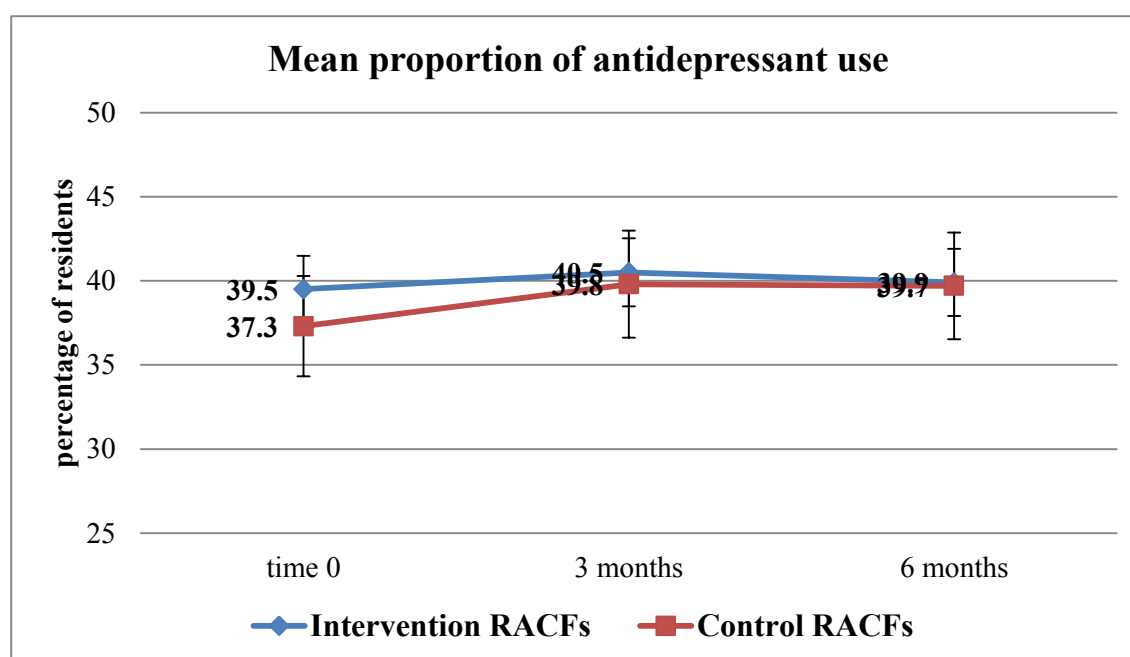
### 22.4.3 Rates of Antidepressant use

There was no significant impact of the RedUSE trial from baseline to time 26 weeks on antidepressant use in either the control or intervention RACF groups; intervention facility mean antidepressant use: baseline; ( $M = 39.5\%$  residents,  $SD = 9.9$ ) to time 26 weeks ( $M = 39.7\%$  residents,  $SD = 8.8$ ),  $t(12) = -0.1$ ,  $p = 0.9$  (two-tailed), and control facility mean antidepressant use: baseline; ( $M = 37.3\%$  residents,  $SD = 6.6$ ) to time 26 weeks ( $M = 39.9\%$  residents,  $SD = 10.0$ ),  $t(11) = -1.4$ ,  $p = 0.2$  (two-tailed). The proportions of residents taking antidepressants in intervention and control RACFs are represented graphically in Figure 22.

The rate of TCA use was examined separately because these agents can be prescribed for their sedative effects. The rates of TCA use decreased slightly over the trial, albeit, non-significantly, in both intervention and control RACFs: intervention RACF mean TCA use: baseline; ( $M = 6.9\%$  residents,  $SD = 3.9$ ) to time 26 weeks; ( $M = 6.1\%$  residents,  $SD = 3.6$ ),  $t(12) = 1.4$ ,  $p = 0.2$  (two-tailed); and control RACF mean TCA use: baseline; ( $M = 10.9\%$  residents,  $SD = 8.0$ ) to time 26 weeks; ( $M = 10.3\%$  residents,  $SD = 8.1$ ),  $t(11) = 0.9$ ,  $p = 0.5$  (two-tailed).



**Figure 22: Mean proportion of antidepressant use in intervention vs. control RACFs**



#### 21.4.4 Summary of the effect of the RedUse intervention on psychotropic prevalence

Table 68 provides a summary of the rates of psychotropic utilisation in both intervention and control RACFs at the commencement of the project, and upon the project's conclusion. Significant differences in prevalence rates are shown in bold font.

**Table 68: Mean psychotropic prevalence rates for intervention and control RACFs at baseline and wk26**

Psychotropic prevalence rate	Intervention RACFs			Control RACFs		
	baseline (%)	Wk26 (%)	<i>p</i> value*	baseline (%)	Wk26 (%)	<i>p</i> value*
Benzodiazepines	31.8	26.9	<b>&lt; 0.001</b>	30.4	33.0	0.2
Antipsychotics	20.	18.6	<b>&lt; 0.05</b>	21.9	23.9	0.2
Overall psychotropic rate	61.1	58.4	<b>&lt; 0.005</b>	62.4	66.3	0.09
Antidepressants	39.5	39.7	0.9	37.3	39.9	0.2
Tricyclic Antidepressants	6.9	6.1	0.2	10.9	10.3	0.5

\* Significant *p*-values (<0.05) are shown in bold font

## 22.5 Prevalence of potentially inappropriate psychotropic prescribing

The number of potentially inappropriate medications for intervention and control RACFs at baseline and at week 26, according to the Beers criteria are listed in Table 69. The RedUSE intervention exerted no effects on the rate of potentially inappropriate antidepressant prescribing; however, the reduction in the number of inappropriate benzodiazepines reduced the overall number of PIMs by approximately a fifth in the intervention RACFs. The difference in the proportion of residents taking PIMs before and after the RedUSE trial was significant in intervention RACFs: 20.5% vs. 16.6% ( $\chi^2 = 4.7$ ,  $df = 1$ ;  $P < 0.05$ ). There was a slight decrease observed in the proportion of residents taking PIMs in the control RACFs before and after the RedUSE trial; however, this difference was not significant: 23.7% vs. 22.4% ( $\chi^2 = 0.3$ ,  $df = 1$ ;  $P = 0.6$ ).

**Table 69: Potentially inappropriate psychotropic prescribing according to Beers Criteria**

	Intervention RACFs		Control RACFs	
	Wk = 0 N = 891	Wk = 26 N = 888	Wk = 0 N = 684	Wk = 26 N = 705
<b>Antidepressants</b>				
Amitriptyline	36	35	40	38
Doxepin	16	14	19	18
Fluoxetine	13	11	13	10
<b>Benzodiazepines</b>				
Flurazepam	-	-	-	-
Temazepam > 15mg	46	34	30	31
Zolpidem > 5mg*	1	1	1	1
Diazepam	48	34	49	47
Chlordiazepoxide	-	-	-	-
Oxazepam > 60mg*	8	6	4	6
Alprazolam > 2mg*	15	11	5	6
Lorazepam > 3mg*	1	1	1	1
Number of PIMs	183	147 ( $p < 0.05$ )	162	158

\*Total daily dose

According to the U.S. long term care facility interpretive guideline criteria, a proportion of antipsychotic and benzodiazepine doses exceeded the maximum recommended geriatric doses at baseline (see Table 70). The RedUSE intervention had minimal impact on the dosing of antipsychotic agents as there was no significant difference in the rate of high-doses prescribed from baseline to week 26 in either the intervention or the control RACFs. The intervention did, however, significantly reduce the proportion of high doses of benzodiazepine agents prescribed

in intervention facilities: 18.0% vs. 12.8%, ( $\chi^2 = 0.9$ ,  $df = 1$ ;  $P < 0.05$ ). There was no discernible change in the proportion of high dose benzodiazepines prescribed in the control RACFs: 17.7% vs. 17.7%, ( $\chi^2 = 0.3$ ,  $df = 1$ ;  $P = 0.6$ ).

**Table 70: Potentially inappropriate psychotropic medication according to U. S. Long-term care facility interpretive guidelines**

Criteria	Intervention			Control		
	Wk 0 N = 891	Wk 26 N = 888	<i>P</i> value	Wk 0 N = 684	Wk 26 N = 705	<i>P</i> value
<b>Antipsychotics</b>						
Chlorpromazine (>75mg)	3	2		-	-	
Haloperidol (>2mg)	10	7		11	10	
Olanzapine (>7.5mg)	21	24		22	20	
Quetiapine (>150mg)	5	5		8	8	
Risperidone (>2mg)	10	10		23	22	
<i>No of excessive doses</i>	49	52	0.7	64	60	0.6
<b>Benzodiazepines</b>						
Diazepam (>5mg)	45	25		35	36	
Alprazolam (>0.75mg)	15	11		5	6	
Oxaxepam (>30mg)	44	35		34	36	
Temazepam (>15mg)	46	34		30	31	
Nitrazepam (>5mg)	10	9		17	16	
<i>No of excessive doses</i>	160	114	<0.05	121	125	0.9

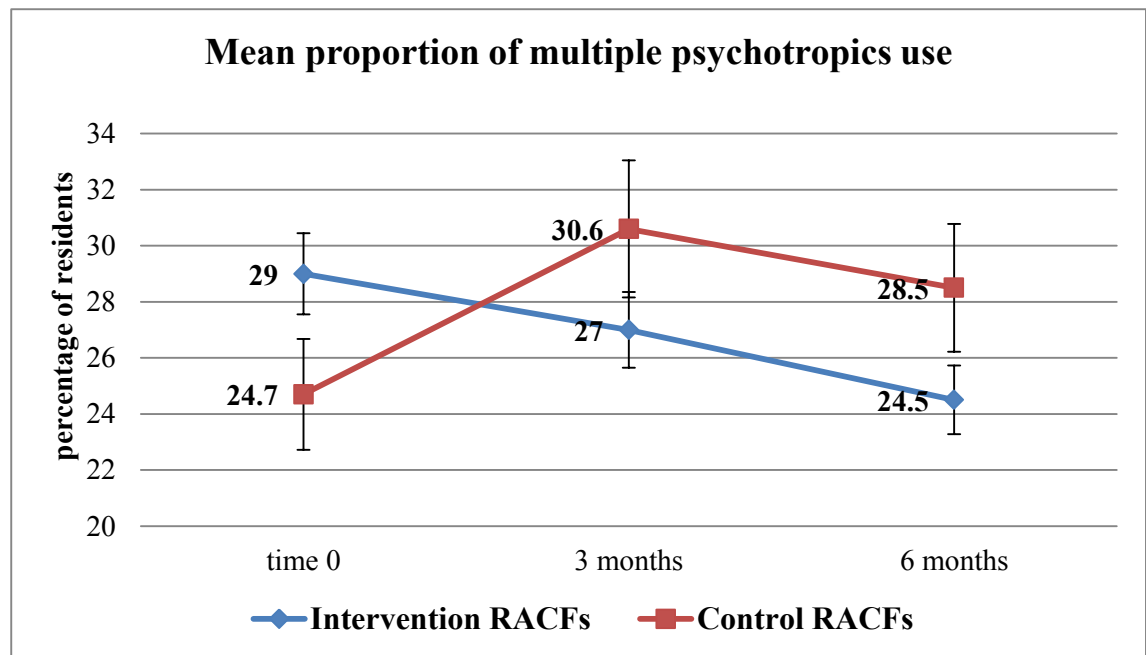
## 22.6 Prevalence of multiple psychotropic use

The Mean proportion of residents taking two or three or more psychotropic agents was also evaluated (see Figures 23 and 24).

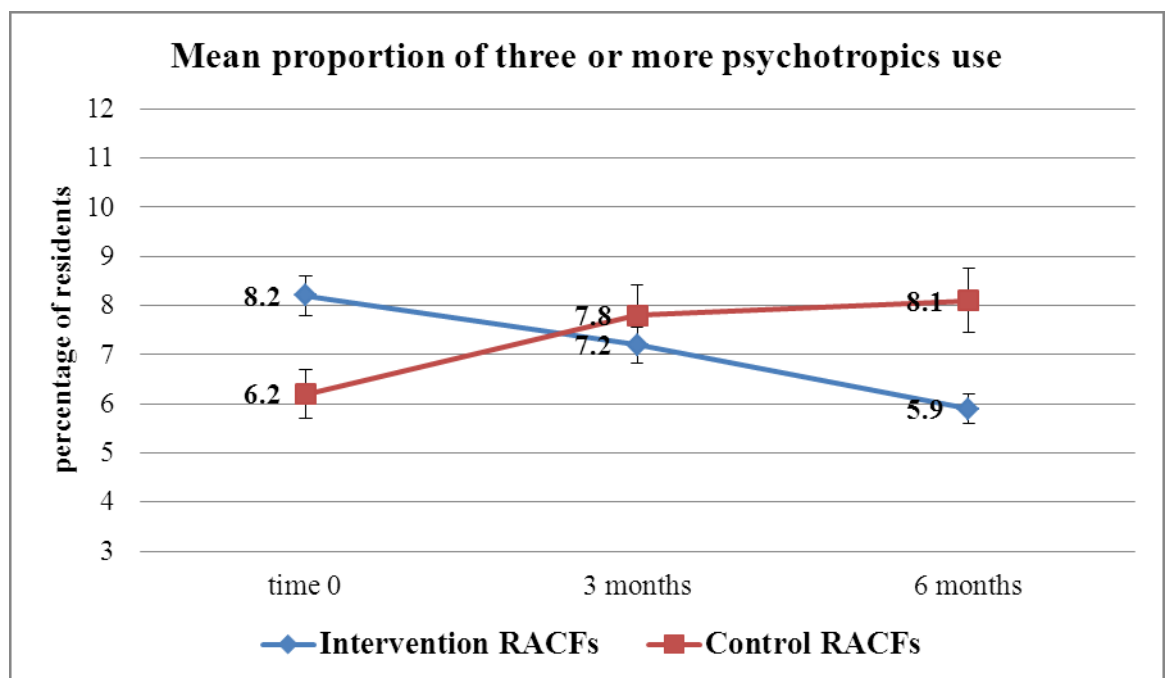
There was a decrease in the mean proportion of multiple psychotropic use (i.e. use of two or more psychotropic agents) in intervention RACFs from baseline ( $M = 29.0\%$  residents,  $SD = 9.3$ ) to time 26 weeks ( $M = 25.5\%$  residents,  $SD = 7.6$ ) which was significant:  $t(12) = 2.7$ ,  $p < 0.05$ . Results of the 2-way, repeated measures ANOVA confirmed a statistically significant effect of the intervention on the use of two or more psychotropic agents ( $p < 0.01$ ).

A significant decrease was also noted in the proportion of residents in intervention RACFs taking three or more psychotropic agents at baseline ( $M = 8.2\%$  residents,  $SD = 3.4$ ) to time 26 ( $M = 5.9\%$  residents,  $SD = 3.7$ ),  $t(12) = 2.7$ ,  $p < 0.02$  (two-tailed). Results of the 2-way, repeated measures ANOVA also showed a statistically significant effect of the intervention on the use of three or more psychotropic agents ( $p < 0.005$ ).

**Figure 23: Mean proportion of multiple psychotropic use in intervention vs. control RACFs**



**Figure 24: Mean proportion of three or more psychotropic agent use in intervention vs. control RACFs**



Although increases in multiple psychotropic measures in the control RACFs were seen over the trial, these were not significant: Baseline mean multiple psychotropic use (i.e. use of 2 or more psychotropic agents): ( $M = 27.4\%$  residents,  $SD = 8.0$ ) to time 26 weeks ( $M = 28.5\%$  residents,  $SD = 8.9$ ),  $t(11) = -0.7$ ,  $p = 0.5$  (two-tailed), and baseline mean use of three or more

psychotropic agents: ( $M = 6.2\%$  residents,  $SD = 3.5$ ) to time 26 ( $M = 8.1\%$  residents,  $SD = 5.7$ ),  $t(11) = -1.7$ ,  $p = 0.1$  (two-tailed).

### 22.6.1 Co-administration of antipsychotics and benzodiazepines

As a further measure, the proportion of residents in each facility taking antipsychotics and benzodiazepines together was examined. As with other measures, the proportion of residents taking both antipsychotic and benzodiazepine medication decreased in the intervention RACFs over the trial period, whereas the prevalence rate of this combination therapy increased in the control facilities. This variation in rates can be seen in Figure 25.

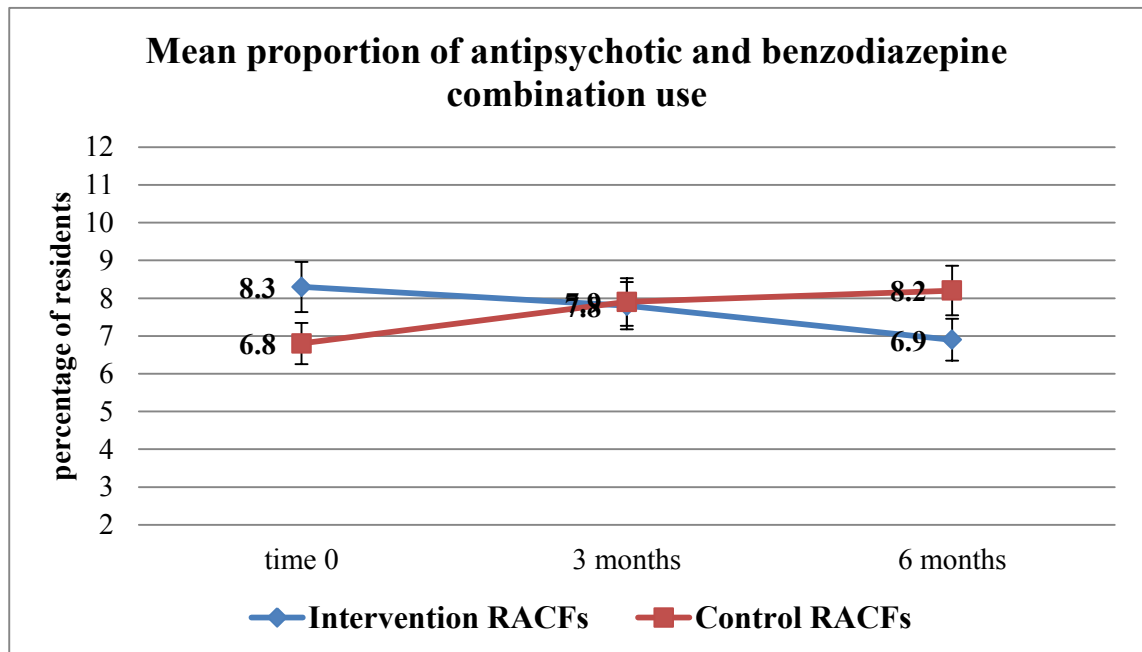
There was a statistically significant decrease in the mean proportion of antipsychotic and benzodiazepine combination therapy used in intervention RACFs from baseline ( $M = 8.3\%$  residents,  $SD = 5.2$ ) to time 26 ( $M = 6.9\%$  residents,  $SD = 4.5$ ),  $t(12) = 2.4$ ,  $p = 0.03$  (two-tailed). However, the 2-way repeated measures ANOVA showed that the effect just missed out on statistical significance ( $P = 0.06$ ). There was no significant difference in the proportion of residents taking both antipsychotics and benzodiazepines in the control RACFs from baseline; ( $M = 7.0\%$  residents,  $SD = 5.0$ ) to time 26 ( $M = 8.2\%$  residents,  $SD = 5.2$ ),  $t(11) = -1.22$ ,  $p = 0.3$  (two-tailed).

Table 71 summarises the effect of the RedUse intervention on multiple psychotropic use.

**Table 71: Mean multiple psychotropic prevalence rates for intervention and control RACFs at baseline and wk26.**

Psychotropic prevalence rate	Intervention RACFs			Control RACFs		
	baseline (%)	Wk26 (%)	<i>p</i> value*	baseline (%)	Wk26 (%)	<i>p</i> value*
<b>2+ psychotropics</b>	29.0	25.5	<b>&lt; 0.01</b>	27.4	28.5	0.5
<b>3+ psychotropics</b>	8.2	5.9	<b>&lt; 0.005</b>	6.2	8.1	0.1
<b>antipsychotic + benzodiazepine</b>	8.3	6.9	0.06	7.0	8.2	0.3

**Figure 25: Mean proportion of combination antipsychotic and benzodiazepine use in intervention vs. control RACFs**



## 22.7 Dose variation

The variation in doses throughout the trial was measured in all thirteen of the intervention RACFs but was only able to be measured in eleven control RACFs. The reason for this missing data was because the RedUSE psychotropic audit program was deleted in one of the control pharmacies at week 26, meaning that the resident dosages at this particular RACF could not be tracked by their assigned trial identification number.

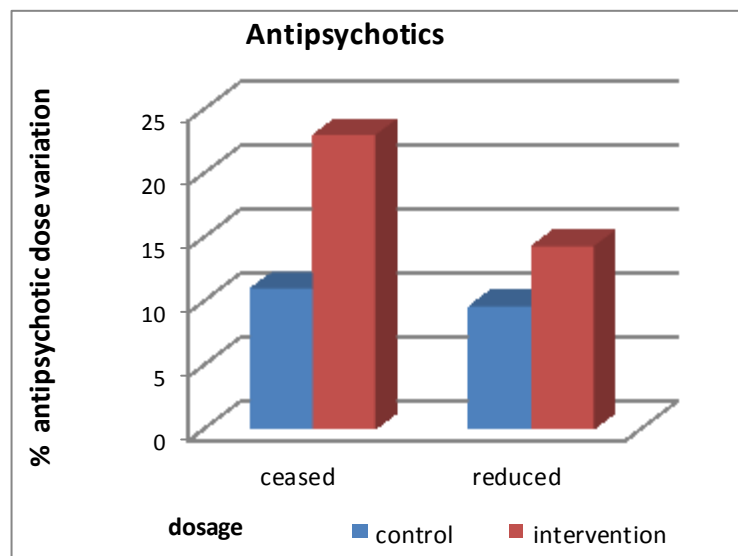
The medications and dosages of residents with three measures of medication use at baseline, 12 and 26 weeks had their dosage ‘tracked’ for this analysis of dosage variance. A total of 154 residents with all three audit measures were taking antipsychotics at baseline in the intervention aged care facilities. In the control RACFs, 115 residents with three audit measures in total were taking antipsychotics at baseline. Table 72 outlines the dosage variation of antipsychotic medication in both intervention and control RACF groups. It can be seen that nearly a quarter of residents taking antipsychotics at baseline had their antipsychotic ceased in the six months of the intervention project, a figure double that of the control group. On the other hand, 16.5% of the control residents taking an antipsychotic at baseline had their doses increased during the project compared to only 4% of the intervention residents.

**Table 72: Variation in resident antipsychotic use in intervention vs. control RACFs**

Antipsychotic Agents	Intervention RACFs	Control RACFs
	Baseline to week 26 N (%)	Baseline to week 26 N (%)
Drug ceased	35 (22.7)	13 (11.3)
Dose increased	6 (3.9)	19 (16.5)
Dose decreased	22 (14.3)	11 (9.6)
Same dose	91 (59.1)	72 (62.6)
<b>Total</b>	<b>154 (100)</b>	<b>115 (100)</b>

In the intervention RACFs, antipsychotic doses were more likely to have been ceased or reduced, and doses less likely to have been increased when compared to the dosage variation pattern found in control RACFs. The difference in antipsychotic dose variations between the intervention and control groups was found to be very significant ( $\chi^2 = 17.4$ , (df=3),  $p < 0.0005$ ). When the number of residents in each RACF group who had their antipsychotic dose ceased or reduced over the duration of the RedUSE trial was compared, a substantial difference was noted between the intervention and control facilities (36.9% vs. 20.9%,  $\chi^2 = 7.4$ , (df=1),  $p < 0.01$ ). The reduction/cessation of antipsychotic doses is charted as Figure 26.

**Figure 26: Antipsychotic doses ceased/reduced in intervention vs. control RACFs**



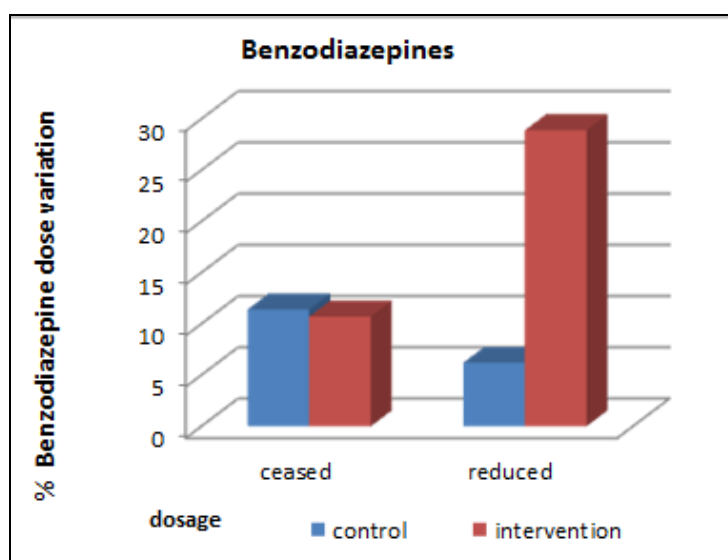
The dose variation of benzodiazepines in the RedUSE intervention RACFs was even greater than the antipsychotic dose variation. A total of 280 residents in intervention facilities, and 176 residents in control facilities were taking benzodiazepines at baseline. Table 73 shows the dosage variation of benzodiazepines in both intervention and control RACF groups when the benzodiazepine doses taken by this sample of residents were tracked over the three DUE measurements.

**Table 73: Variation in residents' benzodiazepine use in intervention vs. control RACFs**

Benzodiazepine Agents	Intervention RACFs	Control RACFs
	Baseline to week 26 N = 280 (%)	Baseline to week 26 N = 176 (%)
Drug ceased	30 (10.7)	20 (11.4)
Dose increased	17 (6.1)	28 (15.9)
Dose decreased	81 (28.9)	11 (6.2)
Same dose	152 (54.3)	117 (66.5)
<b>Total</b>	<b>280 (100)</b>	<b>176 (100)</b>

Nearly 40% of benzodiazepine doses in residents of intervention RACFs were reduced or ceased outright during the trial compared to 17% of doses in control RACFs. Conversely, 16% of control residents taking benzodiazepines at baseline had their dose increased over the same period, whereas only 6% of intervention residents had their benzodiazepine dose increase. The difference between benzodiazepine dose variations in the intervention and control groups was found to be very significant when tested with a two way chi-squared test ( $\chi^2 = 41$ , (df =3),  $p < 0.0001$ ). When the number of intervention residents who had their benzodiazepine dose ceased or reduced was compared to the same data in the control residents, there was a very significant difference (39.6% vs. 17.6%,  $\chi^2 = 23.4$ , (df =1)  $p < 0.0001$ ). The reduction/cessation rate of benzodiazepine doses is displayed as Figure 27 overleaf:

**Figure 27: Benzodiazepine doses ceased/reduced in intervention vs. control RACFs**



### 22.7.1 Variation in dosage equivalents

When the Mean chlorpromazine and diazepam equivalents were calculated for each RACF at baseline, week 12 and week 26 and tested with student's t-test a significant difference was found between the intervention RACF dose equivalents before and after the intervention.



However, the difference in dose equivalences found in the control RACFs was not significant. The mean dose equivalence of both antipsychotic and benzodiazepine agents decreased in the intervention RACFs, whereas this measure increased slightly in intervention RACFs.

There was a statistically significant decrease in the mean chlorpromazine equivalence ( $M = \text{mg/day/resident}$ ) of RACFs from baseline ( $M = 21.5$ ,  $SD = 12.9$ ) to time 26 ( $M = 17.1$ ,  $SD = 9.9$ ),  $t(12) = 4.2$ ,  $p = 0.02$  (two-tailed). However, the 2-way repeated measures ANOVA only showed a trend towards statistical significance ( $P = 0.09$ ).

The decrease in the mean diazepam equivalence in intervention RACFs from baseline ( $M = 3.8$ ,  $SD = 1.2$ ) to time 26 weeks ( $M = 2.9$ ,  $SD = 1.0$ ), was also significant:  $t(12) = 3.1$ ,  $p < 0.01$  (two-tailed). Results of the 2-way, repeated measures ANOVA for the intervention group RACF data showed a statistically significant effect of the intervention on mean diazepam equivalence ( $p < 0.005$ ).

Although increases in mean equivalence ( $M = \text{mg/day/resident}$ ) measures in the control RACFs were seen over the trial, these were not significant: Mean chlorpromazine equivalence: baseline ( $M = 24.9$ ,  $SD = 11.3$ ) to time 26 weeks ( $M = 27.2$ ,  $SD = 15.4$ ),  $t(11) = -0.6$ ,  $p = 0.5$  (two-tailed); and baseline mean diazepam equivalence: ( $M = 2.9$ ,  $SD = 1.0$ ) to time 26 weeks ( $M = 3.2$ ,  $SD = 0.7$ ),  $t(11) = -1.1$ ,  $p = 0.3$  (two-tailed).

The variation in mean equivalents over the RedUse trial is shown in Tables 74 and 75:

**Table 74: Variation in resident mean chlorpromazine dose equivalence use in intervention vs. control RACFs over time**

Mean chlorpromazine equivalence	Intervention RACFs (chlorpromazine equivalence, SD) ( $M = \text{mg/day/resident}$ )	Control RACFs (chlorpromazine equivalence, SD) ( $M = \text{mg/day/resident}$ )
Wk 0 (baseline)	21.6 (12.9)	24.9 (11.3)
Wk 12	18.1 (10.1)	24.7 (11.1)
Wk 26	17.1 (9.9)	27.2 (15.4)

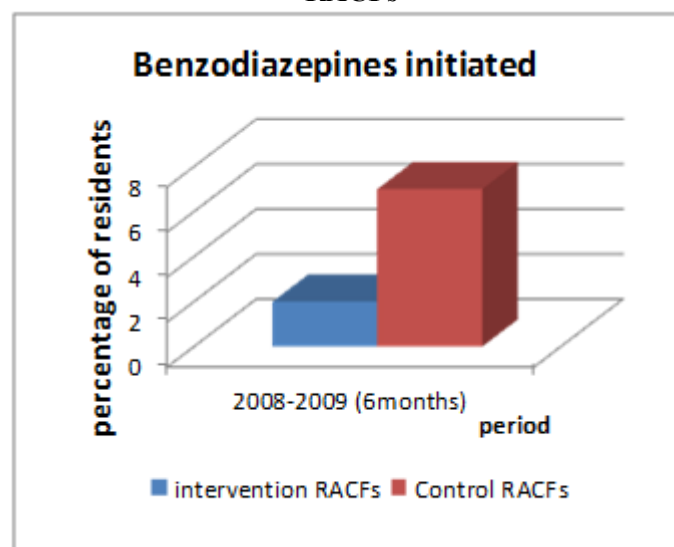
**Table 75: Variation in resident mean diazepam dose equivalence use in intervention vs control RACFs over time**

Mean diazepam equivalence	Intervention RACFs (diazepam equivalence, SD) ( $M = \text{mg/day/resident}$ )	Control RACFs (diazepam equivalence, SD) ( $M = \text{mg/day/resident}$ )
Wk 0 (baseline)	3.8 (1.2)	2.9 (1.0)
Wk 12	3.3 (0.9)	3.1 (0.9)
Wk 26	2.9 (1.0)	3.2 (0.7)

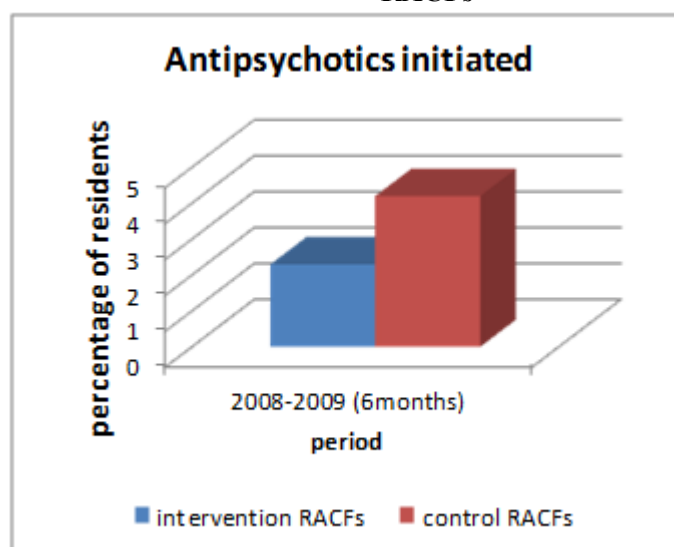
### 22.7.2 Initiation of antipsychotic or benzodiazepine therapy

Throughout the six month duration of the RedUSE trial, a lower proportion of residents in the intervention RACF were started on antipsychotic or benzodiazepine medications than their control counterparts. When a chi-squared test was applied to this data it was found that significantly fewer residents in intervention facilities started benzodiazepine treatment than residents in control facilities (2.1% vs. 7.0%,  $\chi^2 = 21.9$ , (df=1),  $p < 0.0001$ ). However, the difference in the proportion of residents starting antipsychotic treatment between RACF groups did not reach statistical significance (2.3% vs. 4.2%,  $\chi^2 = 2.8$ , (df=1),  $p = 0.09$ ). Figures 28 and 29 illustrate the difference in the proportion of antipsychotic and benzodiazepine sedative agents initiated from baseline to week 26.

**Figure 28: Proportion of residents initiated on benzodiazepines in intervention vs. control RACFs**



**Figure 29: Proportion of residents initiated on antipsychotics in intervention vs. control RACFs**



## **22.8 Basic costing analysis**

The basic cost analysis report was commissioned from an independent economic analyst, Mr Peter Brownscombe, who consulted with the research team before preparing a preliminary costing analysis report, attached as Appendix T. In broad terms, the main results, from a cost of medicines perspective, are shown Table 76, which shows the costs of antipsychotics and Table 77, which shows costs of benzodiazepines.

**Table 76: Details of antipsychotic consumption during the 6 months study**

	Control		Intervention	
	Week = 1	Week = 26	Week = 1	Week = 26
Number of residents	684	705	891	888
Total cost of antipsychotics for patients per month (30 days)	\$11,452	\$12,339	\$12,630	\$12,849
Average cost per patient per month (30 days)	\$16.74	\$17.50	\$14.18	\$14.47

In terms of the costs of antipsychotic medication, the average costs per patient increased slightly in both the control RACF group (4.5%) and the intervention RACF group (2%) over the course of the 26 weeks. This was attributed to a few residents being switched over from the typical antipsychotic haloperidol to olanzapine. It was of interest to note that the costs of antipsychotic medications in the intervention group were 15% lower than in the control group at the start of the trial.

**Table 77: Details of benzodiazepine consumption during the 6 months study**

	Control		Intervention	
	Week = 1	Week = 26	Week = 1	Week = 26
Number of residents	684	705	891	888
Total cost of benzodiazepines for patients per month (30 days)	\$2,007	\$2,377	\$3,434	\$2,886
Average cost per patient per month	\$2.93	\$3.37	\$3.85	\$3.25

Some particular conclusions can be extracted from an examination of Table 77 relating to benzodiazepine use. To start, the costs per resident increased in the control group (15%) over the course of the 26 week trial. However, the average costs of benzodiazepine treatment per

resident decreased by 15% in the intervention group over the course of the 26 weeks. It should be noted, though, that the costs in the intervention group were 31% higher than in the control group at the commencement of the trial.

The results from the RedUSE trial revealed that the average resident monthly cost of benzodiazepines was \$3.38 – which works out to 78 cents per week. If this was reduced by 15%, this cost would fall by 11 cents per resident per week. This converts to a potential saving per resident of \$5.72 per year. If an assumption is made that there is a high level of homogeneity of RACF residents across Australia, it is possible to suggest an extrapolation from the “intervention” group in Tasmania to the Australian population. This requires a calculation to estimate both the current average cost/resident and the potential saving/average resident over a year by a reduction in their benzodiazepine medication cost by 15%. With almost 6000 residents in Tasmanian RACFs, the total potential savings could approach \$35 000 per annum for the state alone. This calculation does not factor in other parameters such as a potential reduction in the number of falls and improvements for the residents in terms of quality of life measures.

The preliminary cost analysis although very basic, serves to indicate that widespread implementation of the RedUSE program, with successful reduction of psychotropic rates, offers the potential to be cost effective; however, more detailed financial analysis is required before definitive conclusions can be made. The principal benefits of the RedUSE project are more likely to be non-financial, though it appears that, given increases in sedative costs, there are still potential cost savings to be achieved in Australia more generally, by implementing elements of the RedUSE program.

## **22.9 Qualitative Evaluation**

An important outcome measure of the RedUSE project was the acceptance of its key strategies. To gauge acceptability, two focus groups were held in March 2009 with participants involved in the intervention arm of the project. One group was conducted with directors of Nursing (DON) of the RACFs and clinical nurses, and the other with participating community pharmacists. All trained pharmacists and DONs involved with the intervention RACFs were invited to attend the focus groups on successive evenings in March 2009. Both focus groups were facilitated by an independent qualitative researcher, to ensure open feedback from the participants. It was felt that the participants would be less likely to reveal their true perceptions of the project if the project manager and key researcher was there. However, before the focus groups were held, the qualitative researcher met with the project manager to determine the main objectives of the qualitative analysis and to develop two interview schedule outlines. The two main objectives of the focus groups were:

- To determine the success of strategies and implementation procedures used in the RedUSE project; and
- To ascertain any barriers and enablers to the RedUSE project.

Eight out of the ten RedUSE-trained pharmacists agreed to join the pharmacist focus group. Nine nursing staff from nine of the thirteen intervention RACFs participated in the nursing staff focus group. The results of the focus group analysis are derived from the final report of the qualitative analysis and the interview transcripts, and are grouped in key themes as follows:

### **22.9.1 Perceptions of the RedUSE project**

Both pharmacists and nursing staff were initially hesitant over the perceived workload associated with RedUSE. However, the nurses maintained they were very keen to start the project and any apprehension was not well founded once the study was commenced.

*“I think when we got the detail we thought, oh okay that’s going to be fine, it was all steam ahead basically” Nurse*

Pharmacists were concerned about their capacity to participate in the program but agreed to participate because their RACF had indicated interest, and also because of the remuneration offered.

*“My main fear was how on earth was I going to try and fit this in and do this around everything else and do a good job?” Pharmacist*

*“The first thing I looked at was the financial incentives because I knew it was going to take time and the fact that it adequately covered costs for pharmacists going to RACFs. I thought it was pretty worthwhile and pretty easy from the word go and you get paid to do the training sessions down at the RACF. Well I can get someone to come in and do my shift then I can go down there and do the training.” Pharmacist*

### **22.9.2 Training**

Prior to RedUSE, the community pharmacists had provided only limited training to RACF nursing staff. The only instances recalled involved medications for Parkinson’s and cardiovascular disease. Pharmacists valued the training they received prior to the commencement of RedUSE. They reported that the speakers were of high quality, the

information provided was very useful and the remuneration was important for pharmacists' participation.

*“Yes, the training that was provided with the project was relevant, it was a great quality, you came away after a day-and-a-half and thought that was a good day-and-a-half; it was inspiring, there were so many benefits.”* Pharmacist

Most pharmacists said they enjoyed delivering the staff educational sessions and found the resource material ‘easy to use’. In several cases it was the first time the pharmacists had used a PowerPoint® presentation. The training material gave them confidence as the content had been well researched.

*“It was fabulous material to deal with and if you had a laptop to show them all the pictures; it was easy, it was very conducive to discussion and they (the nursing staff) said you should be doing more of this on other topics.”* Pharmacist

The feedback from the Nurse focus group was that the pharmacy education sessions were beneficial and well received by the nurses. Nurses also felt that having their supply pharmacist deliver the educational sessions promoted participation.

*“It was really visual and it was quick as well, like it didn't take too long, you know I mean in the aged care environment it's hard to capture everybody's attention you know ...compared to other training, I mean I could see the interest, like just actually looking around the room and seeing how they were engaged in it, and also the attendance, it was the first time I think I had every single RN and EN at the home, all sitting there.”* Nurse

*“Our staff have a rapport with that supplying pharmacist. To have them come in, because the registered staff knew them, oh [name]'s going to come, you know, so there was that willingness if you like, would you agree, to go along and listen to what this proposal you know was all about.”* Nurse

### **22.9.3 Psychotropic audit and checking medication records at the RACF**

The procedure of using the RedUSE software program was well accepted by pharmacists. Pharmacists were also required to visit their RACF to verify sedative use. One particular facility seemed threatened by one pharmacist's visit and a nurse was asked to accompany her, however, this was an isolated incident. The pharmacists did, however, comment that they did not find the process of entering 'PRN' sedative usage into the program to be very streamlined. It seemed to

be a cumbersome process and the pharmacists needed to enter a specific start date of administration and this was not always available. Both pharmacists and nurses found the DUE reports to be very interesting and useful as it enabled a sedative comparison across different aged care facilities.

*“We only knew which number we were, we didn’t know which number other facilities were, so it was helpful to say, “well look guys this is us, in comparison to these”, and you know I’m sort of in the middle so there were people above and below me, so I could say well look we’re not real bad ... but we’re not really good either because we weren’t number 1, so there’s obviously room, lots of room for improvement.” Nurse*

#### **22.9.4 Sedative review plan**

Both groups discussed the Sedative Review Plan forms (see Appendix S) in detail. Initially, it was not clear to some nurses what information was required on the forms to the extent that pharmacists in a few places were asked to assist them. Some forms were completed quickly, whereas in others, completion was slow. One nurse offered the following explanation on the difficulty she found in completing the forms;

*“I think there was a time issue. A lot of facilities out there at the moment really struggling to find staff, ... and then they get agency staff and agency staff aren’t there enough to probably make a decent comment on a form like that, because they are not with the residents long enough or on a regular basis.” Nurse*

Nursing staff reported that they found the forms useful in assisting nursing staff to review why patients were receiving sedatives.

*“I think it prompted that thought process, before you just tended to dish out the pills without really thinking.” Nurse.*

A few GPs did not respond well to the sedative review forms and in some cases wrote sharp comments in their comment sections of the form. However, most GPs seemed to be accepting and in some cases were enthusiastic of the initiative.

*“Some of the GPs, ... we had a run of them, just came straight in and said right ‘Let’s do it’. Let’s do it, and they just took people off pills.” Nurse*

*“Our doctors that have been involved in this they’ve really got really into it and they’ve actually raised the awareness, and they really are looking at it, whereas I didn’t feel that they were doing that before.” Nurse*

Many of the nurses were appreciative of being asked to comment on the forms when often they were not considered in such matters.

*“I would say maybe in the past .. that the comment of the registered nurses actually is not even included, it’s actually forgotten.” Nurse*

*“I think (it gave nurses a voice), absolutely, and because of the project the doctor was actually compelled really to come in and actually say well what do you think Sis, I’ve got this form that says on here that you know Joe Blow does this you know, is that right and let’s talk about it, or you know you don’t think that he might need that dose or whatever the case may be” Nurse*

#### **22.9.5 RedUSE newsletter and resident/relative pamphlet**

While both groups were reasonably positive about the content of RedUSE newsletters there was evidence to suggest that distribution within some RACFs was inconsistent. Similarly, while the residents’ pamphlet was useful when given to patients’ relatives in case conferences, few residents may have read them; however, when used, they were beneficial.

*“It’s been helpful the pamphlets and the brochures and things that have gone with the RedUse project, especially the resident one. Like I had a difficult resident who wanted to have Temaze sort of like 2 o’clock and 3 o’clock in the morning, ... he’d been doing this for such a long time, and so I got all the notes and the pamphlet and all that sort of stuff and finally, he sat down and he read it all and now, he’s actually done it.” Nurse*

#### **22.9.6 Barriers to RedUSE-ing**

Few barriers were reported related to RedUSE project. However, both nurses and pharmacists found that the attitudes of some of the nursing staff and GPs were the main obstacle to reducing sedative medication.

*“They (two night nursing staff) were the most oppositional people that I’d ever come across, so they’re at the other end of the extreme where they just were ‘I just want an easy life; I come here to read my night sheet and I don’t want any hassle’.” Pharmacist*



*“There's a bit of a leap there, that some aren't prepared to take, do you know what I mean, there's a resistance, at times, only with some” Nurse*

*“Somehow you put the suggestion and when the GPs ring you they make it very clear that these guys are in the waiting room to heaven and let's just keep them comfortable...One of the GPs is just like that and he had 15 patients there. It is really hard to change that attitude.” Pharmacist*

### **22.9.7 Enabling factors and barriers to the RedUSE project**

The enabling factors and barriers to the RedUSE project were identified in the qualitative focus groups. These factors were identified by the independent qualitative researcher conducting the focus groups and were included in his final report. This allows an independent non-biased analysis of the opinions of the pharmacists and nursing staff involved in the project. The enabling factors were identified as follows:

#### *22.9.7.1 Enablers*

- As benzodiazepine and antipsychotic use in Hobart RACFs was regarded as greater than necessary and past attempts to alter this usage reported to be minimal: community pharmacists and nurses therefore accepted the rationale for the RedUSE project.
- The majority of RACFs in both Intervention and Control groups were willing to participate in the RedUSE project. Although many facilities stated that they appreciated the funding received, the principle motive for taking part was the desire for education about medication and to meet accreditation standards. The majority of RACFs have been advised in reports from accreditation agencies that the level of sedative prescribing was too high.
- The pharmacists were highly appreciative of the training and support offered throughout the project, with many commenting that they would be happy to participate in other initiatives involving other topics if they were offered a similar level of training, support and remuneration to the RedUSE project.
- Many of the nursing staff stressed that they were supportive of the training because it was conducted by their community pharmacist who also supplied their medications and that they were familiar with. Many stressed that their communication with the pharmacy was enhanced as a result of the project.
- Nursing staff also felt more qualified to approach the resident's GPs after the training provided by the RedUSE project. Several of the pharmacists mentioned that there was a real 'hunger' for information about medications from the nursing staff at the RACFs.

#### **22.9.7.2 Barriers**

Barriers which may have reduced the impact of the RedUSE project were:

- In a few RACFs, there were issues with the timing of service provision. Although the audit activity in facilities and completion of sedative review forms were well accepted, several RACFs commented that the timing of audits would best be coordinated with facilities in advance of a pharmacy visit to ensure they are conducted with nursing staff knowledge and at convenient times.
- The Sedative review plan was introduced as an alternative to case conferences. Nursing staff and pharmacists felt that more consideration should be given for additional training to nursing staff on how to complete the review plans. Moreover, there needs to be an improved mechanism for the circulation of sedative reviews forms so the comments made are current and not relate to what could be past sedative use.
- Some of the GPs and nursing staff were resistant to changes in sedation use and can thus hinder the implementation of projects that promote review of these medications in RACFs.
- Many of the nursing staff and pharmacists commented that they wished they had more time to devote to reviewing resident medication use and considering alternative approaches to sedative medication. Additional Nursing Staffing resources were required to allow staff time perform some of the key strategies of the RedUSE project such as the sedative review plan.
- It was challenging to engage the GPs to be active participants in the project. Nursing staff did comment that most of the GPs were supportive of reviewing and reducing sedative use when prompted by nursing staff. However, further research is needed to evaluate the enablers and barriers for GP involvement in such interventions in order to involve this important health professional group to a greater extent.

#### **22.9.8 Conclusions from the independent analysis of the RedUSE project**

The following concluding comments were contained in the qualitative research final report. Overall, participants of the focus groups suggested that the RedUSE project had some very positive effects on the RACFs. These were that:

- It increased the focus on sedative use in aged care, made staff re-evaluate the need for sedatives and refocussed the need for regular reviews of sedative use;
- It highlighted that sedatives can be reviewed in RACFs without detrimental effects to patients;

*“The ones that we tended to, they just stopped yeah, and they weren’t missed, most of them, in fact I don’t remember anyone going back on them again.” Nurse*

- RedUSE provided a framework so that stakeholders in the use of sedatives in residents could effectively act as a group which may not have been possible individually;
- It improved the education of nurses and pharmacists on sedative use and its possible consequences;
- It showed that community pharmacists could provide worthwhile education to RACF staff when supplied with suitable training materials, support and background information;
- It increased community pharmacist and nurse confidence, so that they could challenge routine practices;
- It enabled some RACFs to show accreditation committees that they had undertaken a positive quality use of medicines project.

*“A couple of weeks ago we had our accreditation and as I say we’re just a small facility and the accreditors who came were quite impressed that for, a couple of reasons, that we actually could be bothered to do, or that we did some research, because we’re only a small, little facility, and they were impressed with the feedback that was given from the staff, so for you guys that are going for accreditation I can’t recommend it more highly” Nurse*

## CHAPTER TWENTY THREE: DISCUSSION

### AN INTERVENTION TO IMPROVE QUALITY PSYCHOTROPIC USE IN RACFS

The RedUSE project was a novel intervention study which evaluated the impact of pharmacist-led QUM services on RACF psychotropic rates. The RedUSE project strategies, including psychotropic audit, nursing staff education and interdisciplinary sedative review, successfully reduced benzodiazepine and antipsychotic use in our intervention RACF group when compared to our control RACF group. Further, the project significantly increased the number of sedative dosage reductions. Both findings corroborate the positive effect of previous international intervention studies in RACFs which utilised similar strategies of nurse education and interdisciplinary communication.<sup>42,558,581</sup> This finding also validates the role of community pharmacists in ensuring quality use of psychotropic medication in RACFs.

#### **23.1 Antipsychotic and benzodiazepine prevalence rates**

The rate of benzodiazepine use in intervention facilities fell by 15% over the 6 month trial period. The rate of antipsychotic use fell by 8%. These reductions were admittedly modest in scale, yet they were shown to be statistically significant in contrast to control homes where overall rates of use increased. Although the rates of both antipsychotic and benzodiazepine use significantly declined as a consequence of the RedUSE project, the effects on benzodiazepine rates of use and dosage variation were more profound than the effects observed with antipsychotic use. The same difference in effect size between benzodiazepine and antipsychotic measures was also witnessed across the majority of secondary outcome measures, including the appropriateness of medication measures and the rate of psychotropic agent initiation.

A similar observation was made by Nishtala *et al.* in their meta-analysis of studies focusing on the impact of education and medication review on psychotropic drug use in RACFs. Nishata *et al.* reported that the pooled effect size of these interventions on hypnotic benzodiazepine use was statistically significant; however, although individual studies demonstrated a statistically significant reduction in antipsychotic medication use, the meta-analysis of the pooled effect size failed to demonstrate a specific effect.<sup>68</sup> Nishtala *et al.* theorised that antipsychotics were more difficult to ‘reduce’ than hypnotics because BPSD was harder to manage than sleep disturbance, and that there were few effective alternative options for treatment.<sup>68</sup>

In the present study it should be noted that the baseline rate of antipsychotic use in the sample of Tasmanian RACFs was quite low in comparison to that found in other prevalence studies, nationally and internationally. Professor Snowden reported that 28% of residents were

administered antipsychotics in 44 Central Sydney RACFs in 2009.<sup>623</sup> Likewise, Somers *et al.* and Nishtala *et al.* reported a 33% and 23% RACF prevalence in Western Australian and Sydney, respectively, in 2008/9.<sup>379,397</sup> Similarly, in Austria, Germany and New Zealand, the reported antipsychotic prevalence was 46%, 28% and 24% respectively in the last five years.<sup>418-420</sup> The baseline antipsychotic prevalence in the present study was only 20%; however, by the end of the trial this figure had decreased further to 18.6%. This makes the Tasmanian RACF rate of use one of the lowest reported in the literature for the past 5 years. However, this may mean there is limited potential for rates to fall much further.

On the other hand, there was significant potential to decrease benzodiazepine prevalence in the sample of Tasmanian RACFs, although rates of use had already fallen by the time RedUSE was launched. The proportion of residents taking benzodiazepines in stage one of this thesis in 2006 was 40%; however, by the time the RedUSE project was started in 2008 the baseline RedUSE benzodiazepine use in intervention and control RACFs had fallen to 32%, representing a 22% decline in use over a two year period. The main reason for this marked decline was thought to be related to significant media publicity associated with the initial findings and an increased focus on reducing benzodiazepine use by accredited pharmacists (see Appendix U). Snowdon *et al.* attributed media attention on their initial study as one of the reasons for the large decline in benzodiazepine use observed in Central Sydney.<sup>395</sup> Nonetheless, in spite of this marked fall in benzodiazepine use, the prevalence rates at the start of RedUSE, at 30% - 32%, were higher than that found in Central Sydney (15%), Western Australia (28%) and New Zealand (12%) in a similar time frame. One of the reasons for the greater decline in benzodiazepine than antipsychotic use was that there was simply more scope to impact benzodiazepine rates of use. It should also be acknowledged that the major focus of all educational content was on benzodiazepine agents, in particular.

### **23.2 Substitute sedative agents**

Several researchers have suggested that when antipsychotic and benzodiazepine rates are reduced other psychotropic agents may be prescribed for their substitute sedative effects.<sup>581,585</sup> For this reason the impact of the project on antidepressant prevalence was evaluated, as some of these agents, TCAs, for example, can be prescribed for their sedating properties.<sup>312</sup> Substitute prescribing of alternate agents in place of antipsychotics and benzodiazepines did not appear to occur as the prevalence of antidepressant use in the intervention facilities was consistent throughout the trial, in both the intervention and control RACF groups, with the rate of TCA use actually decreasing slightly in both groups.

### **23.3 Potentially inappropriate medication use**

The RedUSE intervention also significantly reduced the number of potentially inappropriate medications (PIMs) prescribed in the intervention RACFs according to both the Beers criteria and the U.S. Long-Term Care Facility Interpretive Guidelines.<sup>359,409</sup> In all, a 20% drop in the number of PIMs, as categorised by the Beers criteria, was observed in intervention RACFs, with the number of benzodiazepines exceeding recommended dosages decreasing by 29%. This reduction in PIM use was not observed in the control group of RACFs. Upon closer inspection of the data it can be seen that the main reason for the drop in PIMs was related to the changes made to benzodiazepine medication throughout the trial. Fewer long-acting benzodiazepines were prescribed and the proportion of excessive dosages also declined significantly. There were no discernible reductions in either potentially inappropriate antipsychotic or potentially inappropriate antidepressant use. This finding provides additional evidence of the greater impact of the intervention on benzodiazepine use than antipsychotic use.

Two recent intervention studies have also succeeded in reducing the level of PIM prescribing in the RACF setting.<sup>624,625</sup> The first study was a 12-month pharmacy-led intervention RCT conducted in 22 RACFs in Northern Ireland in which clinical pharmacists identified at-risk residents and worked collaboratively with nursing staff and GPs to review the use of psychotropic medication.<sup>624</sup> After 12 months there was a significant ( $P < 0.001\%$ ) difference in the proportion of residents taking PIMs in the intervention group (20%) when compared to the control group (50%).<sup>624</sup> The second study was conducted in a single large RACF (204 bed) in Switzerland and was nurse-led.<sup>625</sup> After a 1-hour combined training session for GPs, DONs and nursing staff, nurses identified PIMs and requested modifications from GPs. By 4 months the PIM prescription rate in residents had decreased from 14.5% to 2.8%.<sup>625</sup> These two recent studies and the RedUSE study clearly demonstrate that the interdisciplinary approach offers an effective means to reduce the level of PIM prescribing in RACFs.<sup>624,625</sup>

### **23.4 Prevalence rates of multiple psychotropic use**

Apart from generating a significant reduction of antipsychotic and benzodiazepine rates and PIMs, the RedUSE project also had a positive impact on reducing the use of overall psychotropic and multiple psychotropic medications. The administration of two or more psychotropic agents taken by residents decreased by 12%; with the use of three or more psychotropic agents decreasing by 28%. Though in real terms the numbers of residents taking three or more psychotropic agents were small this is a significant finding as multiple psychotropic agent usage is reported as the highest ranked medication-related risk factor for falls in RACFs.<sup>81,626</sup>

The impact of the intervention strategies on the rate of combination antipsychotic and benzodiazepine therapy was also evaluated. There is some evidence to suggest that benzodiazepine co-administration with antipsychotic medication may be a risk-factor for increased mortality associated with antipsychotic use in older people with dementia.<sup>627</sup> Moreover, another research team found that residents with Alzheimer's disease taking the two agents together experienced a faster rate of cognitive deterioration than those residents taking a single agent.<sup>628</sup> The significant reduction recorded in the rate of co-prescribing of antipsychotics and benzodiazepines in the majority of intervention RACFs, may have positively impacted on the mortality and cognitive functioning of the residents. In the present thesis, measures on cognitive function and mortality were not collected. If this intervention is to be repeated in the future, it is hoped to collect standardised cognition measures and detailed mortality and morbidity data so the benefits of reducing multiple psychotropic use can be assessed.

### **23.5 Variation after review of sedative medication**

The majority of guidelines on the use of antipsychotics for BPSD stress the importance of regularly reviewing usage and trialling dose reduction/cessation every 6 -12 weeks.<sup>96,164,629</sup> Prescriptions for benzodiazepines should generally be time-limited with long-term users of benzodiazepines encouraged to reduce dosage at regular intervals.<sup>95</sup> A recent follow-up of the DART-AD found that long-term antipsychotic users (longer than 12 months) with dementia had a significantly increased risk of mortality.<sup>266</sup> The researchers of the DART-AD trial '*emphasised the urgent need to put an end to unnecessary and prolonged prescribing*' of antipsychotic agents.<sup>266</sup> It is therefore pleasing to observe that one of the outcomes of the RedUSE project was a marked increase in the number of antipsychotic and benzodiazepine dosages reviewed, with a more than doubling of dose reductions/cessations in intervention RACFs when compared to control RACFs.

The study in Stage two of this thesis observed that only 25% of antipsychotic and benzodiazepine doses were reduced, or agents ceased, over a year of data collection. In the intervention RACFs, RedUSE resulted in 40% of benzodiazepine and 37% of antipsychotic doses being reduced or agents ceased outright in a six month period. These rates of dose variation in intervention were double that observed in the control RACFs, at 18% (benzodiazepines) and 21% (antipsychotics). The differences in the reduction of dose equivalents between intervention and control RACFs confirmed this overall reduction in doses of both agents.

The qualitative research conducted as stage three of this thesis had indicated reluctance by most of the nursing staff (and many of the GPs) to reduce doses of psychotropic medication when a resident was stabilised, contrary to professional guidelines. In recognition of this factor,

the RedUse project always emphasised that the main aim was not to make wholesale changes but simply to trial a small dose reduction in those residents who were on antipsychotics and benzodiazepines for extended periods, in order to evaluate if the resident could be managed on a lower dose. If the resident exhibited a worsening in their symptoms, whether it be behaviour, anxiety or sleep disturbance, then their regular dose could be resumed. In this way, the change to the existing review practice was easier to accept and nurses and GPs were aware that medications could be reinitiated if required.

### **23.6 Initiation of new psychotropic medication**

Interestingly, although the focus of the RedUse project was on reducing psychotropic medication, the project also impacted the prescribing of new psychotropic medication. In the RedUse intervention facilities 2.3% of residents were initiated on antipsychotic medications and 2.1% were started on benzodiazepine medications over the six month period of the trial, when compared with 4.2% and 7% of control residents started on antipsychotic and benzodiazepines, respectively. Although the actual numbers of residents initiated on new medication was quite small, it is relevant to note that a project based largely on nursing staff education can have an impact on new prescribing and provides additional evidence to support the hypothesis that nursing staff exert a large influence when these medications are initiated.

### **23.7 Strategies of the RedUse project**

There were three main strategies involved with the RedUse trial. The strategy of clinical audit was shown to have limited impact on RACF antipsychotic use in Crotty *et al*'s Australian study, possibly because the results were fed back solely to GPs attending facilities, nursing staff input was not included and there was limited education provided to assist participants to know what was considered good practice psychotropic prescribing.<sup>396</sup> However, the use of medication audits presented to inter-disciplinary hospital staff meetings, accompanied with education, proved to be an effective strategy to reduce benzodiazepine prescribing in the acute hospital setting, with one research team reporting a marked reduction in prevalence rates from 36% to 31% of patients over a 3-month period.<sup>589</sup> The positive outcomes of the RedUse project suggest that the use of clinical audits targeted at nursing staff, and supported by staff education and interdisciplinary review, can reduce psychotropic use and increase the number of attempts at dose reduction/cessation of these agents in the RACF setting as well as the hospital setting.

Each of the three main strategies of the RedUse project deserves consideration as follows:



### **23.7.1 The RedUSE clinical audit**

The NPS has developed two clinical audits or ‘Drug Use Evaluations’ for use by nursing staff or other health practitioners in RACFs. DUEs on benzodiazepines and antipsychotics have been developed for use in RACFs; however, their DUE audit is paper-based, can be time-intensive for staff and is not targeted for one specific professional group.<sup>607,608</sup> Moreover, the NPS DUEs are not benchmarked so individual facility performance cannot be compared to that of other RACFs. Further these DUE audits are not reinforced by staff feedback or training on ‘best practice’ use of these medications.

The RedUSE psychotropic audit software application, on the other hand, requires minimal staff input as it ‘extracts’ existing community pharmacy dispensing information and converts this data into a benchmarked report; the results of which are subsequently feedback to nursing staff in an educational session. Given the present nurse staffing constraints in aged care, and the fact that pharmacists are being encouraged to ‘*become more involved in the monitoring and review of psychotropic medication*’ by government, the RedUSE computerised psychotropic audit program offers a timely, convenient and potentially cost-effective method of obtaining an audit measure and disseminating the findings to nursing staff.<sup>486</sup>

### **23.7.2 Sedative Review Plan**

Another strategy of the RedUSE project involved a dedicated ‘sedative review plan’ for those residents taking antipsychotic and benzodiazepine medication for extended periods. It could be argued that the Australian Government presently has a funded system of pharmacist provided medication review services operating in RACFs and that this ‘sedative review’ may be a duplication of this program. However, the RedUSE ‘sedative review plan’ differs from the current RMMR in several ways. Firstly, the sedative review plan targets psychotropic medication use specifically, whereas RMMRs consider all medications. Further, and most importantly, nursing staff comments are an integral component, whereas the present RMMR system is specifically intended to involve communication between GPs and pharmacists alone. Finally, pharmacists do not have to undergo the accreditation process to complete ‘sedative review plans’, unlike with RMMRs, allowing a greater number of community pharmacists to promote quality use of psychotropic medication in the residential aged care setting.

Roberts *et al.* reported a significant reduction in benzodiazepine prevalence in their trial of RACF pharmacist-led medication reviews which became the model for the present RMMR system.<sup>42</sup> It should be noted though, that a significant amount of staff education (amounting to 26 hours per facility) was also delivered to intervention RACFs in this particular intervention.<sup>42</sup> Although one of the main justifications for the present ‘RMMR’ system is that reviews can reduce psychotropic use in RACFs, there is limited evidence to show that RMMRs, as a stand-

alone strategy, can result in a reduction of antipsychotic or benzodiazepine use.<sup>49,87</sup> One of the reasons for this is that the present RMMR system only involves and funds dialogue between GPs and pharmacists. Nursing staff, who appear to be very influential in the use of psychotropic medication, are usually not involved.<sup>87</sup> In the qualitative stage of this thesis one of the accredited pharmacists interviewed expressed his opinion that the most effective and valuable medication review occurred when the GP, pharmacists and nursing staff were actively involved. The RedUSE 'sedative review plan', which actively seeks nursing staff input, is supported by staff education and audit feedback to staff, appears to be a more effective method to reduce the use of psychotropic medications specifically than the current RMMR system.

There is an individualised targeted medication review scheme that has proved successful in reducing benzodiazepine use in the community, known as the Veteran's 'MATES' program.<sup>590</sup> In 2002, the Australian Department of Veterans' Affairs sent an individualised list of veterans receiving long-acting benzodiazepines to GP prescribers, along with drug information on how to review and reduce the use of these medications.<sup>591</sup> As a result, the use of long acting benzodiazepines in these targeted veterans was reduced by 35% six months after the feedback program was initiated.<sup>591</sup> The RedUSE 'Sedative Review Plan' adopts a similar approach in providing and promoting review in targeted residents of RACFs taking antipsychotic and benzodiazepine medications for extended periods. Like the Veterans program, the sedative review plan is also supported by a tailored educational program. However, the RedUSE targeted sedative review plan differs from the Veterans program in several key areas.<sup>590</sup> To start, nursing staff comments are a necessary component of the RedUSE sedative review process, in recognition of nursing staff influence on psychotropic use, whereas nursing staff input is not sought in the Veterans program even if the veteran is in a RACF. Further, the RedUSE sedative review plan encourages three health professional groups to communicate in an interdisciplinary way, a way of working which is heavily promoted by Australian health policy. Finally, the sedative review plan is initiated by community pharmacy and an external organisation is not involved in the process, significantly reducing infrastructure costs and allowing targeted review to be accessible to all residents of RACFs, not just the veteran population.

The Sedative review plan was introduced as an alternative to case conferences which were vetoed by the Advisory committee. During qualitative post-analysis of the project nursing staff and pharmacists felt that more consideration should be given for additional training to nursing staff on how to complete the review plans. Some of the GPs opted not to complete the plan and some nursing staff did not follow the correct procedure in regards to distribution. Admittedly, the sedative review plan was not an original aspect of the trial and was added retrospectively. This probably accounts in part for the lack of training and adequate support

allocated to the strategy. If the sedative plan strategy is utilised again, greater effort will be directed to ensuring that adequate training and support is given to ensure the strategy can be used more effectively.

### **23.7.3 Nursing staff education**

The OAMHP quiz provided to staff before the RedUSE project gave an indication that the level of knowledge of nursing staff about psychotropic medication, particularly knowledge related to side effects and recommended duration of use, was quite poor. Indeed, several of the pharmacists commented that they were surprised at the lack of understanding about medications demonstrated by the nursing staff during the educational sessions, with one of the pharmacists commenting, for example, that none of the nurses in her educational sections knew about the link between benzodiazepines and falls. One positive aspect of the RedUSE trial was that the majority of pharmacists reported that their RACFs were very keen to host and promote the educational sessions and there was a real desire to learn more about psychotropic use and medications in general.

Multi-strategic educational interventions have been shown to be an effective strategy to reduce both antipsychotic and benzodiazepine use in RACFs, with effective education based on guideline implementation and feedback to an interdisciplinary health care team.<sup>87</sup> The RedUSE educational sessions on psychotropic medications were well accepted by the RACF staff and pharmacists. One of the key aspects of the educational sessions was that they were delivered by community pharmacists who already had an existing relationship with the facility nursing staff and attending GPs. Nursing staff reported that staff were willing to participate in the educational sessions not only because they wanted more information about medications but they were also curious to hear what their pharmacist had to say. Not only did these educational sessions promote the review of psychotropic medication but participants of the RedUSE trial felt that they enhanced the professional relationship between the community pharmacy supplying the RACF and the nursing staff.

Another benefit of the RedUSE education strategy was that community pharmacists were trained, equipped and supported to deliver this education. Many pharmacists involved in the project admitted that they had not delivered formal educational sessions to RACF staff before. The success of the RedUSE training was also reflected in comments made by community pharmacists, who were keen to provide, and nursing staff, who were very keen to participate, in similarly formatted educational sessions on other 'pharmacological' topics.

### **23.8 The auxiliary strategies of the RedUSE project**

Apart from the psychotropic audit, staff education and the sedative review plan, the RedUSE project also included promotional strategies such as the launch event, the distribution of newsletters, dissemination of guidelines, academic detailing for GPs and the production and distribution of resident and relative pamphlets about benzodiazepines. It is difficult to assess the impact of these auxiliary strategies, although qualitative feedback indicates that both pharmacist and nursing staff participants considered these strategies to be complementary, but not essential, to the key strategies of audit, education and sedative review. In many of the intervention RACFs these strategies were not adopted. For instance, several nursing administrators at several intervention RACFs admitted to not reading and distributing the RedUSE newsletters. In addition, many of the GPs approached were not interested in attending a session on academic detailing, citing a lack of time and adequate reimbursement as their reason. Finally, although the nursing staff members were supportive of the resident and relative pamphlets, only one of the nurses said she had given one to a resident. Further research is needed to assess the barriers to the use of these types of strategies.

### **23.9 A combination of strategies**

The nurses and pharmacists participating in the two focus groups were most supportive of the three key strategies of the RedUSE project; the psychotropic clinical audit, educational sessions and the sedative review plan. It appears that the combination of these three strategies worked synergistically to produce the positive outcomes of the project.

It is essential to note that the RedUSE psychotropic audit program was installed in both intervention and control RACFs and that all facilities received a customised benchmarked report regarding their psychotropic use. Despite receiving this prescribing information, the control RACFs recorded an overall increase in sedative rates of use. It could thus be argued that the simple provision of a clinical audit report is not sufficient on its own to impact prescribing rates. The audit strategy appears to require the additional support of other strategies such as an educational program and/or targeted sedative review to have positive effect. Similar assertions have been made by reviewers of other RACF intervention trials.<sup>68,600,602</sup>

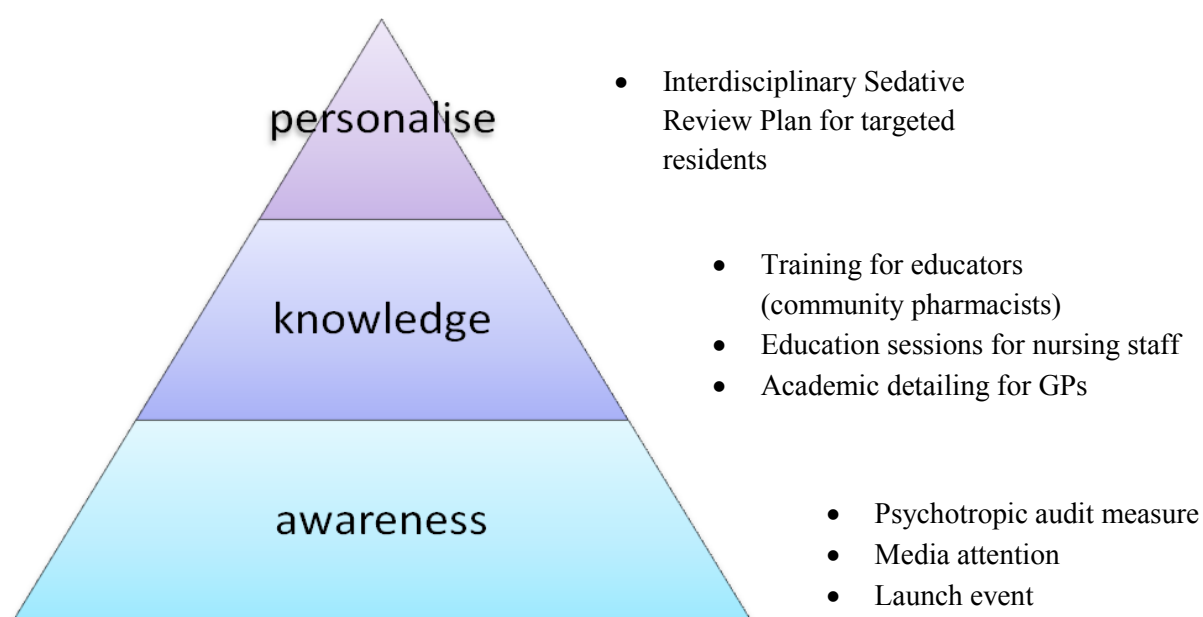
The psychotropic audit measure provided an overall picture of the pattern of antipsychotic and benzodiazepine use in each RACF. This information was then benchmarked and presented to nursing staff, along with education about the benefits and risks associated with these medications and non-pharmacological strategies to manage BPSD, sleep disturbance and anxiety. The final strategy, the targeted sedative review plan, allowed nursing staff to apply their enhanced knowledge at an individual level to participate in the review of the antipsychotic

and benzodiazepine use of their residents. Figure 30 below illustrates the key steps and progression of the RedUSE project's three main strategies:

### **23.10 Potential applications**

The key strategies of the RedUSE project, specifically audit feedback and staff education, could be easily adapted for other therapeutic applications in residential aged care. In fact, the strategies used in the RedUSE project could be incorporated into an implementation kit for pharmacies supplying medications to RACF. In the focus groups, and in informal feedback to research staff, members of nursing staff suggested other topics that could be covered included bowel management and diabetes control. The RedUSE project also has the potential to be conducted in other regions of Australia and, indeed, in other countries where prescribing data can be measured and benchmarked and where healthcare systems are open to interdisciplinary training approaches.

**Figure 30: A schematic diagram of RedUSE intervention project strategies**



### **23.11 The role of pharmacists to improve the quality use of psychotropic medicines in RACFs**

The Commonwealth and NSW governments have voiced concern about the over-use and limited review of antipsychotic and benzodiazepine agents in RACFs.<sup>39,486</sup> Accordingly, both levels of government identified a role for pharmacists to promote the appropriate use and review of antipsychotic and benzodiazepine agents.<sup>39,486</sup> Academic research has also shown that

interventions involving pharmacists as part of an interdisciplinary team, have resulted in the reduction of RACF psychotropic use.<sup>87</sup> The RedUSE trial provides further evidence that community pharmacists can effectively promote the quality use of psychotropic medication in the residential aged care setting.

Each pharmacy participating in the RedUSE project was asked to provide information about the number of RMMRs and associated QUM services supplied to their RACFs. The provision of RMMRs in the control and intervention groups was virtually identical prior to, and during the project. The pattern of QUM service provision was also very similar between control and intervention RACFs, although the majority of community pharmacies did not offer facilities formalised training sessions, audits or other services besides informal talks. Some of the pharmacies admitted they did not offer QUM services at all. In spite of the RMMR service contract and QUM services provided, the rates of antipsychotic and benzodiazepine use were high in the majority of the project's RACFs. Similarly high rates of use of antipsychotic use are still reported in Sydney since the introduction of these enhanced pharmacy services.<sup>623</sup>

The majority of Pharmacists in written evaluations of RedUSE educational sessions and in the focus group commented that they appreciated having a professional, ready-made program of strategies to provide. Although there is a small range of materials available to pharmacists to use for QUM services produced by professional bodies such as the Pharmaceutical Society of Australia and the NPS, these are not accompanied by educational sessions for pharmacists on content or delivery.<sup>607-609</sup> Part of the reason for the limited impact of the present RMMR and associated QUM services on sedative rates, could be attributed to a lack of education and support provided to community pharmacists to be able to provide QUM services effectively.

The success of the RedUSE program illustrates that QUM services provided by community pharmacists, when supported by education on content and instruction on how to effectively deliver these services, can be highly effective at reducing the rate of antipsychotic and benzodiazepine prescribing and promoting review of these medications in RACFs.

### **23.12 Strengths and limitations**

The RedUSE project was specifically targeted to address and reduce the high rate of antipsychotic and benzodiazepine prescribing in RACFs. By targeting nursing staff in particular and incorporating strategies such as audit, feedback and education the project successfully led to a significant reduction in the rate of use of these agents and to other benefits such as an enhanced relationship between pharmacists and nurses at RACFs. However, the RedUSE project had several limitations.

Firstly, it is difficult to distinguish which of the strategies of the RedUSE project had greater impact on reducing antipsychotic and benzodiazepine use in the intervention aged care

RACFs. To do this, researchers would have to test individual strategies in separate intervention studies. The extensive literature review conducted before the project commenced indicated that a multi-faceted approach involving those health professionals involved with in RACFs, namely pharmacists, nurses and GPs, appeared to offer the most substantial chance of success to reduce sedative use; thus, for this reason the research team decided to adopt a similar approach.

It should also be acknowledged that the success of the RedUSE project in reducing sedative use may have been impacted by the publicity attracted from media reports and the visit of Professor John Snowdon. When the University of Tasmania announced the Pharmacy Guild funding for four 'Investigator Initiated' projects, the local newspaper, 'The Mercury' ran a story about the RedUSE project; at the same time, highlighting the risks and limited benefits of sedative use (Appendix U). Likewise, the newspaper and a local radio program ran a story about the Hobart visit of Professor John Snowdon to talk about sedative use in RACFs. Such publicity may have had an independent effect on raising awareness of this issue and contributed to project outcomes. The individual impact of this unsolicited media publicity is difficult to assess.

A further limitation of the project, which may have impacted on the scale of sedative reduction, was related to project timing. Although the second psychotropic measurement was completed by November, some of the pharmacists and RACFs were unable to schedule the second nurse educational session before Christmas. This meant that staff feedback and follow-up education were delivered more than 6 weeks after the second audit collection in five of the intervention RACFs. It was relevant to note that the sedative reduction in these facilities was less than the reduction reported in facilities receiving the educational session at the scheduled time. The delay in the education possibly reduced the momentum and impact of the project in these RACFs. In retrospect, a greater reduction in sedative use would probably have been achieved if the project was commenced earlier and did not run over the Christmas period.

It is also important to recognise that the positive impact of this trial on antipsychotic and benzodiazepine rates in the sample of Tasmanian RACFs may not be transferable to other areas in Australia. It is not possible at this time to compare RACF rates of prescribing from state to state due to the limited number of published prevalence studies and lack of access to national dispensing information.<sup>47</sup> However, there are indications that the rate of benzodiazepine prescribing in Tasmania, in particular, is higher than rates reported in other regions of Australia.<sup>417</sup> As a consequence, there may be more scope for a reduction in the prevalence rate of benzodiazepine medication. It should be noted, however, antipsychotic prevalence rates in Tasmanian RACFs were lower than rates reported in Sydney and New Zealand.<sup>417,420</sup> In spite of this lower baseline rate of antipsychotic use, a significant reduction in use of these agents was observed in intervention RACFs when compared to control RACFs. This positive finding serves to illustrate that the key strategies of the RedUSE project can promote reduced prescribing and

increased review of psychotropic agents in instances when prevalence rates are not elevated in comparison to other areas.

Finally, although the RedUSE project was successful in reducing sedative use there is limited information on the clinical consequences/outcomes associated with the reduction found in the use of antipsychotic and benzodiazepine agents. Interestingly, in the focus group several of the nursing staff mentioned that their falls rate had fallen as a consequence of the project and that behaviours had not appeared to escalate. For this reason, the research team aimed to examine fall rates and the incidence of challenging behaviours in participant facilities immediately before and immediately after the RedUSE trial, in order to assess the impact of RedUSE on clinical outcome measures.

### **23.12.1 GP participation**

Another limitation of the RedUSE project which deserves individual attention was the limited GP participation shown. For instance, although over 140 GPs were invited to the launch event, only 18 GPs attended. The majority of the GPs approached for an academic detailing session also declined to participate or did not attend pre-arranged sessions. This lack of GP participation in educational initiatives was most likely due to the high workload of GPs, and perhaps a certain degree of professional education ‘saturation’. However, it should also be noted that there has been difficulties with GP participation in the RACF setting reported for some time due to issues with shortages of GPs, part time working preferences and a lack of remuneration.<sup>36</sup>

In the two post-intervention focus groups the nursing staff and pharmacists said that some GPs were not supportive of the project and some had ignored their recommendations to reduce sedative medication without comment. Likewise, several complaints were received by the RedUSE researchers from GPs about the sedative review forms. One GP sent one of the review forms back to the university with the comment ‘*stop trying to be a doctor*’ written on the form. Another GP complained in a phone call that he already had to put up with RMMRs and now he had received another pharmacist-generated recommendation.

A recent Australian study has revealed GP resistance to follow pharmacist medication review recommendations in RACFs, especially in the area of mental health. When Nishtala *et al.* performed a retrospective study of 500 randomly selected RMMRs to assess the GP acceptance of pharmacist recommendations, they reported that only half the recommendations to withdraw hypnotics or to monitor for adverse drug reactions associated with antipsychotics, were implemented.<sup>630</sup> Nishala *et al.* theorised that because mental and behavioural disorders in older people were complex it was possible that GPs may not feel confident to manage residents’ mental health conditions on their own and may require specialist involvement before medications were altered.<sup>630</sup> Another reason is probably related to the fact



that prescribing has traditionally been the role of the GP for many years and there is resistance to other professionals '*questioning their professional capability*'.<sup>55</sup> This was one of the barriers identified to GP involvement in Campbell's evaluation of the RMMR program published in 2010.<sup>55</sup>

Another reason why opposition was encountered from GPs to the sedative review forms may have been related to the fact that there was limited face-to-face contact between the pharmacists, the nursing staff and the resident's GP. Many of the recommendations would have been seen for the first time when the GP visited the RACF and checked the resident's case notes, or the sedative review form was received in the mail. A recent evaluation report on RMMRs found that the majority of GPs preferred a collaborative approach when it came to reviewing medications.<sup>55</sup> Most stakeholders felt that improved inter-professional collaboration between GPs, nurses and pharmacists would '*enhance positive health outcomes for residents*'.<sup>55</sup> One of the original proposed strategies of the RedUSE project was an interdisciplinary case conference where the pharmacist, GP and nursing staff could discuss the medications of each resident. Unfortunately, this strategy was considered impractical by the Advisory group. Perhaps, if these case conferences were scheduled as originally planned, the GPs serving the RACFs in the project would be more engaged and communication would be more open between pharmacists, GPs and nursing staff resulting in greater acceptance of the recommended changes in psychotropic use.

In a recent pharmacist-led medication review trial conducted in 22 RACFs in Northern Ireland, 72% of recommendations made by pharmacists about psychotropic medication were implemented. The success of this particular trial was attributed to regular face-to-face collaboration with nursing staff and GPs. Follow-up of all recommendations was also conducted on a monthly basis.<sup>631</sup> To ensure greater impact, future interventions aimed at improving psychotropic prescribing in the RACF setting should include GPs to a greater extent.

### **23.9 Conclusion**

The RedUSE project led to a statistically significant reduction in the proportion of residents in RACFs receiving benzodiazepines and antipsychotics. The number of antipsychotic and benzodiazepine dosages ceased or reduced in intervention RACFs was double that reported in control facilities. The project was well received by the pharmacists delivering the QUM strategies and by the nursing staff participants. The findings suggest that QUM strategies coordinated through community pharmacies, and incorporating the dissemination of local data on medication use, offer an effective approach to reduce psychotropic use in RACFs.

## CHAPTER TWENTY FOUR: CLINICAL OUTCOMES STUDY

### AN INTERVENTION TO IMPROVE PSYCHOTROPIC USE IN RACFS

#### 24.1 Introduction

Although reducing antipsychotic and benzodiazepine use is desirable for many reasons, including meeting RACF accreditation standards and potentially providing cost benefits, there is limited clinical evidence of the benefit of doing this for residents. Ideally, these benefits should manifest as improvements in resident clinical outcomes. Nishtala *et al.* and Markum *et al.* in their recent reviews of interventions to improve RACF prescribing noted there is a pressing need for clinical outcome data showing the benefit for residents in reducing the use of psychotropic agents.<sup>87,587</sup>

The limited information that is available on clinical outcomes when RACF psychotropic medications are reduced provides conflicting evidence. For instance, when Hughes *et al.* performed a retrospective cross-sectional study of RACFs in 4 European countries and Japan, then compared outcome data on falls to similar data from U.S. RACFs, residents in countries where psychotropic use was considerably higher were significantly less likely to fall than residents in the U.S. RACFs, where psychotropic use is lower due to OBRA-87 legislation.<sup>566</sup> Hughes *et al.* attributed this result to the fact that falls rates are impacted by many factors and that many of the non-U.S. RACFs offered better falls prevention strategies than in the U.S.<sup>566</sup> Similarly, Patterson *et al.* reported that falls rates in residents were not impacted when inappropriate psychotropic use was reduced in a recent Northern Ireland intervention RCT.<sup>624</sup> Briesacher *et al.* also noted that fall rates in RACF residents did not alter significantly when benzodiazepine prescribing was reduced markedly in one U.S. state due to funding changes.<sup>579</sup> It is possible, then, that the rate of falls in RACFs may be one clinical outcome that is not impacted by reducing psychotropic rates of use.

On the other hand, Avorn *et al.* reported that measures of cognition in residents improved significantly after psychotropic agents were ceased in a large U.S. intervention trial.<sup>585</sup> And a sizable number of researchers have shown that when antipsychotic agents are withdrawn in RACFs, the frequency of behavioural symptoms does not escalate, and in a few trials, actually improves.<sup>209,466,472,582,583</sup>

The RedUse trial was initially designed to test the impact of a series of community pharmacy-led strategies focused on antipsychotic and benzodiazepine use. Due to the limited scope, funding and human resources allocated to the project, clinical outcome measures were not originally planned to be collected and analysed by the researcher. However, when the final results were analysed, it became apparent that the RedUse project had exerted a significant

impact on psychotropic rates of use. As a consequence, the decision was made to collect retrospective data on the rate of falls and incidents of challenging behaviour from each of the RACFs involved in the intervention RACFs, with the aim of performing a post-intervention analysis.

## **23.2 Aim**

The aim of this first follow-up study was to evaluate the impact of the RedUSE project on falls rates and on the rate of challenging behaviour in RACFs.

## **23.3 Method**

### **23.3.1 Study design**

This study was a retrospective cross-sectional study of clinical outcomes data from RACFs that participated in the intervention group in the RedUSE trial in Hobart during 2008/9.

### **23.3.2 Data collection**

The thirteen intervention RACFs who participated in the RedUSE trial were sent a letter asking them to provide twelve months of audited data on falls and challenging behaviours from April 2008 to April 2009 (attached as Appendix V). This specific period was requested because it comprised clinical outcome data from 3 months before the RedUSE project was initiated, the six month period during which the trial was conducted and 3 months after the trial was completed. It should be qualified that nursing administrators are obliged to audit this data every month to meet the Australian RACF accreditation standards.<sup>45</sup> The information provided by the RACFs was provided as simple counts of the number of falls reported in each RACF each month for twelve months. The same simple count data was collected for incidents of challenging behaviour.

### **23.3.3 Assessment of clinical outcome data**

The RACFs were divided into two categories in regards to reduction in psychotropic prevalence rates resulting from the RedUSE trial. They were classified as either 'responders' or 'non-responders' for both benzodiazepine and antipsychotic agents. This was achieved by calculating the percentage change in antipsychotic and benzodiazepine prevalence rates for all intervention RACFs and then deciding on a cut-off figure for change for a RACF to qualify in either of the categories.

Average fall rate per month figures were calculated for 'pre-trial' data by averaging the number of recorded falls per RACF during the three months preceding the trial. Likewise, the falls rate during the RedUSE trial, referred to as 'trial' data, was calculated by averaging the

number of falls recorded over the last three months of the trial period. The challenging behaviour rate per month was calculated by the same method.

### 23.4 Statistical analysis

The clinical outcome ‘pre-trial’ and ‘trial’ data for falls and for challenging behaviour in the responder groups were then compared to same data for the non-responder groups. The data was statistically analysed with a Wilcoxon Signed Rank test as it was non-parametric. All statistical analyses were performed using StatView®, version 5.0.1 (SAS Institute Inc, Cary NC, USA). ‘P’ values of 0.05 or less were considered statically significant.

### 23.5 Ethical approval

Approval for this particular post trial post outcome analysis was granted by the Human Research Ethics Committee (Tasmania) Network in April 2008; approval number H0009858, as an amendment to the original RedUse study.

### 23.6 Results

#### 23.6.1 Baseline data collection

Twelve out of the 13 RACFs involved in the RedUse study provided data for this post-trial study. One of the RACFs was undergoing accreditation at the time and declined to participate citing a high administrative workload as their reason.

The difference in psychotropic rates in the participant facilities is listed in Table 78. Seven RACFs that achieved a 15% or greater reduction in benzodiazepine use were classified as benzodiazepine ‘responders’, whereas the other five RACFs were classified as benzodiazepine ‘non-responders’. Likewise, seven RACFs that achieved an 8% or greater decrease in antipsychotic use were classified as antipsychotic ‘responders’, whereas the remaining five RACFs were classified as antipsychotic ‘non-responders’.

**Table 78: ‘Responder’ and ‘non-responder’ intervention RACFs. (Responder RACFs are highlighted in bold)**

<b>RACF:</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>
Benzodiazepine Prevalence Change (%)	<b>38</b>	<b>22</b>	<b>21</b>	8	10	-9	<b>24</b>	<b>16</b>	<b>28</b>	-2	-5	<b>46</b>
Antipsychotic Prevalence Change (%)	<b>100</b>	5	<b>8</b>	-2	5	<b>9</b>	<b>11</b>	-1	<b>18</b>	<b>11</b>	<b>17</b>	-64

### 23.6.2 Clinical outcomes

Data on falls and challenging behaviour rates were provided by all twelve RACFs; however, one of the RACFs was not able to be included in the analysis for challenging behaviour as several months of data was missing from their data collection form. When contacted about this, the RACF said that their clinical nurse whose responsibility it was to collect this data had been on extended sick leave over the period where data were missing so it was not collected.

There were large differences in the clinical outcome data between homes which was difficult to explain. For instance, in two RACFs of a similar bed number, the average fall rate per month during the trial was 7.3 and 35.7, respectively. Even in the same facility the rate varied wildly; for example the number of falls in one RACF was 52 in May 2008 and just 7 in April 2009. The variation of challenging behaviour between RACFs and even within some facilities was even more extreme. When the DONs were asked about this marked variation in fall rates they explained that there was no clear definition over what classified as a 'fall', with some facilities classifying a 'slip' as a fall but others not classifying a fall unless it required a GP's assessment. It appeared as if challenging behaviours were also defined and classified in a similar ad-hoc fashion.

### 23.6.3 Falls

The first analysis was performed to assess the effect of a reduction in benzodiazepine prevalence on the average monthly falls rate. The clinical outcome data on 'pre-trial' and 'trial' average monthly falls rate in those RACFs with a greater than 15% reduction in benzodiazepine rates (benzodiazepine responders) and non-responders is presented in Table 79 overleaf.

**Table 79: Average monthly fall rate in benzodiazepine responder and non-responder RACFs**

Responder RACFs		Non-Responder RACFs	
<i>Pre-trial</i>	<i>Trial</i>	<i>Pre-trial</i>	<i>Trial</i>
23.3	28.0	7.6	12.0
10.0	8.7	4.3	6.7
35.6	40.0	7.3	5.7
27.0	9.3	34.0	23.7
23.0	30.3	6.7	8.7
6.0	3.7		
35.7	28.0		
<i>Median:</i>	<b>23.3</b>	<b>7.3</b>	<b>8.7</b>

*Benzodiazepine responder RACFs:* When the average monthly rate of falls before RedUSE and during the latter half of the trial were compared there was no significant difference between the two rates: (*Med* = 23.3, *SD* = 11.5) vs. (*Med* = 28.0, *SD* = 13.7) *Z* = -0.34, *P* = 0.74.

*Benzodiazepine non-responder RACFs:* Likewise, when the average monthly falls rates of the non-responder RACFs before and during the latter half of the trial were compared, there was no significant difference between values: ( $Med = 7.3$ ,  $SD = 12.4$ ) vs. ( $Med = 8.7$ ,  $SD = 7.3$ )  $Z = -0.41$ ,  $P = 0.69$ .

Thus, the reduction in benzodiazepine rates did not appear to significantly impact the rate of falls in participant RACFs that had reduced their benzodiazepine use by over 15%.

A second analysis was performed to assess the effect of a reduction in antipsychotic prevalence on falls rate. The clinical outcome data on ‘pre-trial’ and ‘trial’ average monthly falls rate in those RACFs with a greater than 8% reduction in antipsychotic rates (antipsychotic responders) and non-responders is presented in Table 80 overleaf.

**Table 80: Average monthly fall rate in antipsychotic responder and non-responder RACFs**

Responder RACFs		Non-Responder RACFs	
<i>Pre-trial</i>	<i>Trial</i>	<i>Pre-trial</i>	<i>Trial</i>
23.3	28.0	4.3	6.7
35.6	40.0	7.3	5.7
7.7	12.0	10.0	8.7
27.0	9.3	35.7	40.0
23.0	30.3	6.0	3.7
34.0	23.3		
6.7	8.7		
<i>Median</i>	<b>23.3</b>	<b>7.3</b>	<b>6.7</b>

*Antipsychotic responder RACFs:* When the average monthly rate of falls before RedUSE and during the latter half of the trial were compared there was no significant difference between the two rates: ( $Med = 23.3$ ,  $SD = 11.5$ ) vs. ( $Med = 23.3$ ,  $SD = 12.0.6$ )  $Z = -0.17$ ,  $P = 0.87$ .

*Antipsychotic non-responder RACFs:* Likewise, when the average monthly falls rates of the non-responder RACFs before and during the latter half of the trial were compared, there was no significant difference between values: ( $Med = 7.3$ ,  $SD = 13.1$ ) vs. ( $Med = 6.7$ ,  $SD = 15.2$ )  $Z = -0.41$ ,  $P = 0.69$ .

Thus, the reduction in antipsychotic rates did not appear to significantly impact the rate of falls in those RACFs that had reduced their antipsychotic use by over 8%.

### 23.6.4 Challenging behaviour

The first analysis was performed to assess the effect of a reduction in benzodiazepine prevalence on the average monthly challenging behaviour rate. The clinical outcome data on 'pre-trial' and 'trial' average monthly challenging behaviour rate in those RACFs with a greater than 15% reduction in benzodiazepine rates (benzodiazepine responders) and non-responders is presented in Table 81 overleaf. Please note that data from only 11 RACFs was collected on challenging behaviour rates.

**Table 81: Average monthly rates of challenging behaviour in benzodiazepine responder and non-responder RACFs**

Responder RACFs		Non-Responder RACFs	
<i>Pre-trial</i>	<i>Trial</i>	<i>Pre-trial</i>	<i>Trial</i>
4.7	2.3	0.7	1.7
8.3	6.7	6.0	27.7
11.3	10.0	3.3	22.0
4.3	9.0	8.0	1.7
5.6	4.3	4.3	4.0
6.3	7.0		
<i>Median</i>	<b>6.0</b>	<b>4.3</b>	<b>4.0</b>

*Benzodiazepine responder RACFs:* When the average monthly rate of challenging behaviour before RedUSE and during the latter half of the trial were compared there was no significant difference between the two rates: ( $Med = 6.0$ ,  $SD = 2.6$ ) vs. ( $Med = 6.9$ ,  $SD = 2.9$ )  $Z = -0.73$ ,  $P = 0.46$ .

*Benzodiazepine non-responder RACFs:* Likewise, when the average monthly challenging behaviour rates of the non-responder RACFs before and during the latter half of the trial were compared, there was no significant difference between values: ( $Med = 4.3$ ,  $SD = 2.8$ ) vs. ( $Med = 4.0$ ,  $SD = 12.5$ )  $Z = -0.94$ ,  $P = 0.35$ .

Thus, the reduction in benzodiazepine rates did not appear to significantly impact the rate of challenging behaviour in participant RACFs that had reduced their benzodiazepine use by over 15%.

A second analysis was performed to assess the effect of antipsychotic reduction on the rate of challenging behaviour. The clinical outcome data on 'pre-trial' and 'trial' average monthly challenging behaviour rate in those RACFs with a greater than 8% reduction in antipsychotic rates (antipsychotic responders) and non-responders is presented in Table 82 overleaf.

**Table 82: Average monthly rates of challenging behaviour in antipsychotic responder and non-responder RACFs**

Responder RACFs		Non-Responder RACFs	
<i>Pre-trial</i>	<i>Trial</i>	<i>Pre-trial</i>	<i>Trial</i>
4.7	2.3	6.0	27.7
8.3	6.7	3.3	22.0
0.7	1.7	4.3	9.0
11.3	10.0	6.3	7.0
5.6	4.3		
4.3	4.0		
8.0	1.7		
<i>Median</i>	<b>5.6</b>	<b>5.0</b>	<b>16.4</b>

*Antipsychotic responder RACFs:* When the average monthly rate of challenging behaviours before RedUSE and during the latter half of the trial were compared there was a significant decrease between the two rates: (*Med* = 5.6, *SD* = 3.4) vs. (*Med* = 4.0, *SD* = 3.1)  $Z = -2.00$ ,  $P < 0.05$ .

*Antipsychotic non-responder RACFs:* However, when the average monthly challenging behaviour rates of the non-responder RACFs before and during the latter half of the trial were compared, there was a trend towards an increase in the rate of challenging behaviour between values, but the effect just missed out on being statistically significant: (*Med* = 5.2, *SD* = 1.4) vs. (*Med* = 15.5, *SD* = 10.0)  $Z = -1.8$ ,  $P = 0.07$ .

Thus, the reduction in antipsychotic rates showed a statistically significant impact on the rate of challenging behaviour in those RACFs that had reduced antipsychotic use by over 8%. In those non-responder facilities with only a small decrease in antipsychotic rate or where rates increased there was a slight trend towards increased challenging behaviour.

## 23.7 Discussion

In spite of major limitations in the quality of the clinical outcomes data the results align with those in the published literature. RACFs that reduced rates of benzodiazepine use did not have a corresponding reduction in the rate of falls. Reducing the rate of benzodiazepine use in RACFs did not impact the rates of challenging behaviour either.

The finding relating to falls rates has been demonstrated in several other intervention studies.<sup>566,579,624</sup> Hughes attributed this finding to the fact that falls are impacted by many factors and that altering one of them, that is the rate of benzodiazepine use, may not impact on overall rates of falls.<sup>541</sup> Briesacher *et al.* found that many residents were prescribed substitute agents



which conferred a similar falls risk to benzodiazepines, potentially masking any benefit from reducing benzodiazepine use.<sup>554</sup> Another possibility to account for the lack of impact of reducing benzodiazepine use on falls is that it may well be that long-term users of benzodiazepines become somewhat resistant to the adverse effect of the medications on falls rates. Finally, another possible explanation is that residents become less sedated off medication and therefore become more ambulant, leaving their beds and putting themselves at higher risk for falls. In any case, this present study, and other studies with more robust clinical outcome falls measures suggest that further research is needed before making the generalisation that reducing benzodiazepine rates will result in fewer falls.

When outcomes data were analysed pertaining to antipsychotic use it was found that reducing antipsychotic use also did not impact the rate of falls. Although antipsychotic use has been identified as a risk factor for falls, the reduction in antipsychotic rates in this study was quite small and probably would not have impacted this particular clinical outcome measure to a significant extent.<sup>363</sup>

One of the significant findings of this follow-up study was that the rates of challenging behaviour were lower in those RACFs that had reduced antipsychotic rates. Conversely, in non-responder homes with minimal antipsychotic reduction challenging behaviour rates increased, albeit non-significantly.

Several other studies have found that reducing antipsychotic use has resulted in an improvement in the behaviour in residents.<sup>466,472,473</sup> It may be that when antipsychotics are reduced more attention is given to managing BPSD by non-pharmacological means and that these techniques increase the delivery of 'resident-centred care' thus offering more benefit than medication. It could also be that the antipsychotic medication itself may paradoxically worsen some BPSD. In any case, this finding may allay the concern of many of the health professionals, that reducing antipsychotic use would increase the number of incidents of challenging behaviours.

### **23.8 Strengths and Limitations**

A strength of this study is that it is one of the few to examine the impact of reducing psychotropic medications on the residents themselves, and not just report process measures such as prescribing and monitoring.<sup>587</sup> However, this study has a major limitation in that the quality of the clinical outcome data was poor. It is difficult to make firm conclusions on evidence derived from this nurse-derived audit data. In many of the RACFs there appeared to be no common definition of what falls should be recorded or what incidents of challenging behaviour to audit. This may be acceptable if the same person is collecting the data but, in the year of this data collection, there were a number of staff changes. Thus in a number of RACFs, falls and challenging behaviour data were collected by different people with different interpretations

about what to record or not. In addition, there was no consistency between RACFs in what behaviour or fall was recorded. For instance, in some instances very large homes of over 100 beds per facility recorded falls rates in the single digits whereas much smaller homes (< 40 beds) recorded large numbers of falls.

In future, if this study is to be repeated it is important first of all that clinical outcome measures are planned at the outset as an integral part of the project. Second, it is vital that standardised scales such as the NPI (Appendix A) and the CMAI (Appendix C) are used to measure challenging behaviour and are collected by trained independent researchers. Third, it is important that the rates of falls are measured by a more robust measure such as hospital admission for falls and fracture rates. Finally, an important measure to include that has not been a standard part of evaluations to date is a quality of life measure. The second stage qualitative project showed that antipsychotic and benzodiazepine medications are often used in the belief that these agents improve the quality of life for residents in RACFs. If reducing psychotropic medication was not shown to impact the residents quality of life, as in Ballard *et al*'s antipsychotic withdrawal study, this may go some way to reassure health practitioners that reducing these medications will not cause detriment to their patients.<sup>466</sup>

### **23.9 Conclusion**

In spite of poor quality data, there was an indication that a reduction in antipsychotic rates significantly reduced the number of challenging behaviours reported in the facilities. The reduction of benzodiazepine prevalence associated with the RedUSE trial did not appear to impact the falls rate or the rate of challenging behaviour in intervention RACFs.

## CHAPTER TWENTY FIVE: FOLLOW-UP STUDY

### AN INTERVENTION TO IMPROVE PSYCHOTROPIC USE IN RACFS

#### 25.1 Introduction

The RedUSE project was based on the combined strategies of psychotropic clinical audit, educational sessions and the sedative review plan. One aspect regarding educationally-based interventions, however, that is frequently cited is that their impact is often not sustained without continued intervention.<sup>561,587</sup> For this reason, it is important to conduct follow-up studies of this type of intervention so that the retention of the knowledge gained from the training program can be assessed.<sup>587</sup>

Two recent reviews of interventions to improve RACF prescribing have both noted there is a lack of follow-up studies to assess long-term impact.<sup>87,602</sup> One published follow-up study of an intervention to improve psychotropic prescribing in RACFs was conducted by Schmidt and Fastbom three years after their 1995 controlled intervention study, involving monthly interdisciplinary meetings over a 12-month period.<sup>558,601</sup> In their follow-up study, Schmidt and Fastbom found fewer residents in intervention facilities received hypnotics than residents in control facilities. Several Swedish ‘appropriateness of prescribing’ indicators were also significantly improved, including a reduction in prescribing of three or more medications and fewer non-recommended hypnotics.<sup>601</sup> Although overall prevalence rates of psychotropic use were unchanged from the time of the intervention, it should be noted that Schmidt and Fastbom conducted their follow-up study three years after the original study, an extended period of time which may, in all probability, have diluted the impact of the intervention. Additionally, dosages of psychotropic medication were not considered.

One recent study conducted by Blozik *et al.* followed up the effect of a nurse-led intervention, also based on interdisciplinary education, to reduce inappropriate medications in a large Swiss nursing home, 12 months after the 4-month intervention study was completed.<sup>625</sup> The researchers of this study reported that the prescription rate of inappropriate medications rose, albeit non-significantly, from 2.8% to 4.4% during the follow-up period. Blozik *et al.* also noted that at the 1-year follow-up, like at baseline, benzodiazepines were still the most frequently prescribed potentially inappropriate medication.<sup>625</sup>

Yet, the RedUSE study was not solely an educational intervention. Other strategies such as audit and feedback and interdisciplinary review were also involved. In addition, there were secondary strategies which aimed to increase awareness about the risks and limited benefits associated with psychotropic use in frail older people in RACFs. Media attention was also focused on the project and the topic of sedative use in aged care. Professor Snowden reported

that this type of media attention impacted the rates of benzodiazepine prescribing in Central Sydney, and that rates of use remained low throughout the 15 years since his first psychotropic prevalence study was published. Thus, the main research question underpinning this follow-up study was did the RedUse project have a sustained impact on psychotropic rates of use in RACFs, at least during the first year after the project was completed?

## **25.2 Aim**

The study aimed to evaluate if the effect of the RedUse intervention on antipsychotic and benzodiazepine prevalence, and dosing, was sustained a year after its completion.

## **25.3 Research design**

The 12-month follow-up study was a cross-sectional study of prescribing data achieved by performing a repeat audit of psychotropic medication use in all RACFs that participated in the original study. This prescribing data was compared to data to baseline and trial endpoint (6-month).

### **25.3.1 Setting**

The study design for the original RedUse project was a controlled trial conducted in 25 RACFs in Tasmania. The intervention group included 13 Hobart RACFs and 12 control RACFs that were located in Launceston (the two cities are geographically 180 km apart). The same 25 RACFs were re-audited for the follow-up study.

### **25.3.2 Assessment of psychotropic use**

The primary outcome measure in the RedUse project was the RACF prevalence of antipsychotics and benzodiazepines. Secondary measures were prevalence of antidepressants and the number of dosage variations of antipsychotics and benzodiazepines. The same outcome measures were used for the 12-month follow-up study.

It should be noted that, as dosing information from individual residents could not be linked to previous data due to both computer programming issues and ethical considerations, dose variations could not be evaluated using the same methodology as in Part 2. Therefore, to obtain an indication of dosage change throughout the project and 12 months after its completion, all antipsychotic and benzodiazepine doses were converted into chlorpromazine and diazepam equivalents, respectively. All equivalent doses were calculated using the ‘WHO International classification of Primary Care’ and several other key references.<sup>57,271,487</sup> Where more than one agent in the same psychotropic class was taken by the same resident the dose equivalents were added together. Mean daily equivalent doses for each RACF were calculated

by adding the daily equivalent doses of each RACF resident together and dividing the total by the number of residents taking psychotropic medications from each psychotropic class. The Mean daily equivalent doses for each RACF were compared over three time periods; baseline, end of the intervention project and at the 12 month follow-up period. This was a slightly different methodology to that used in the original RedUSe trial where equivalence measures were calculated per home rather than per resident taking psychotropic medication. The latter measure was thought to be a more accurate indication of doses used in residents taking psychotropic medication.

As before, clonazepam was excluded from our benzodiazepine measures as subsidized supply of this medication is restricted to the management of epilepsy. Similarly, lithium carbonate, clozapine and zuclopenthixol were also excluded as these agents are restricted for the management of schizophrenia or bipolar disorder, where regular dose reductions are not recommended.

### **25.3.2 Data collection**

The RedUSe psychotropic audit software program was modified slightly for the follow-up study and installed at each community pharmacy supplying the participating RACFs. The customized program assimilated community pharmacy dispensing information from RACF medication packaging programs; such as 'Manrex-Webstercare'®. Community pharmacies supplying RACFs use these packing programs to prepare and label resident medications into individualised blistered packs, which are delivered to the facilities and subsequently administered to residents by nursing staff.

The 'data-mined' medication and dosing details were subsequently verified against each resident medication chart by the researchers. Psychotropic medication that was not packed, such as antipsychotic wafers or liquid preparations, was added separately to the database, as were all 'prn' or 'as required' doses. If a 'prn' psychotropic agent was administered on four or more days per week over the past month it was considered to be taken regularly and included in prevalence counts. The outcome measures were then calculated utilising de-identified data obtained from this audit.

### **25.3.3 Recruitment of RACFs**

After ethical approval for the follow-up study was granted, RACFs involved in the original RedUSe study were invited to participate, with all 25 RACFs agreeing to take part in the re-audit. All community pharmacies supplying these facilities also agreed to take part, aside from one pharmacy due to concerns about installing the audit program in their new computer system.

In this particular case, psychotropic data for this RACF was collected via a manual audit of medication charts at the RACF.

## **25.4 Statistical analysis**

The psychotropic prevalence rates and mean daily dosage equivalence of antipsychotics and benzodiazepines of all participant RACFs at the 18-month follow-up were calculated, grouped and then statistically analysed. This data was then compared to data collected from these RACFs at baseline and trial endpoint (time = 6 months).

Antipsychotic and benzodiazepine prevalence and mean daily dosage equivalence outcomes over the 3 data collection periods (baseline, trial endpoint and follow-up) were analysed using two-way (group and time) repeated measures analyses of variance (R-ANOVA), with post-hoc analyses to examine any significant differences across individual time points. Analyses were performed using StatView, v 5.0 (SAS Institute Inc., Cary, NC). *P*-values < 0.05 were considered statistically significant.

## **25.5 Ethical Approval**

The original RedUSE project was registered as a controlled trial at the Australian New Zealand Clinical Trials Registry: registration number: ACTRN12608000221358. Approval for the follow-up trial was granted by the Human Research Ethics Committee (Tasmania) Network: approval number H0009858.

## **25.6 Results**

### **25.6.1 Resident characteristics**

The number of residents in the 13 intervention and 12 control RACFs in the follow-up (18 month) collection period was 863 and 715, respectively, resulting in a total sample of 1578 residents. This sample is consistent with previous sample sizes of 1575 residents at baseline and 1593 residents at trial endpoint (6-month). The number of residents in each intervention RACF ranged from 31-95, with a mean RACF size of 66 beds; whereas the number of residents ranged from 20-118 in the control RACFs, with a mean RACF size of 60 beds.

### **25.6.2 Psychotropic variance**

The antipsychotic and benzodiazepine prevalence measures of the intervention and control RACFs over the three time periods; baseline ( $t = 0$ ), trial endpoint ( $t = 6$  months) and follow-up ( $t = 18$  months) are listed below in Table 83.

**Table 83: Summary of the proportion of residents taking psychotropics from baseline to follow-up (%)**

Psychotropic	Intervention			Control		
	baseline t = 0	trial end t = 6	follow-up t = 18	baseline t = 0	trial end t = 6	follow-up t = 18
<b>antipsychotics</b>	20.3	18.6	20.0	21.9	23.9	18.9
<b>benzodiazepines</b>	31.8	26.9	23.9	30.4	33.0	28.5

The impact of the project on antipsychotic and benzodiazepine dosages used in the RACFs over the three time periods can be seen in Table 84 overleaf.

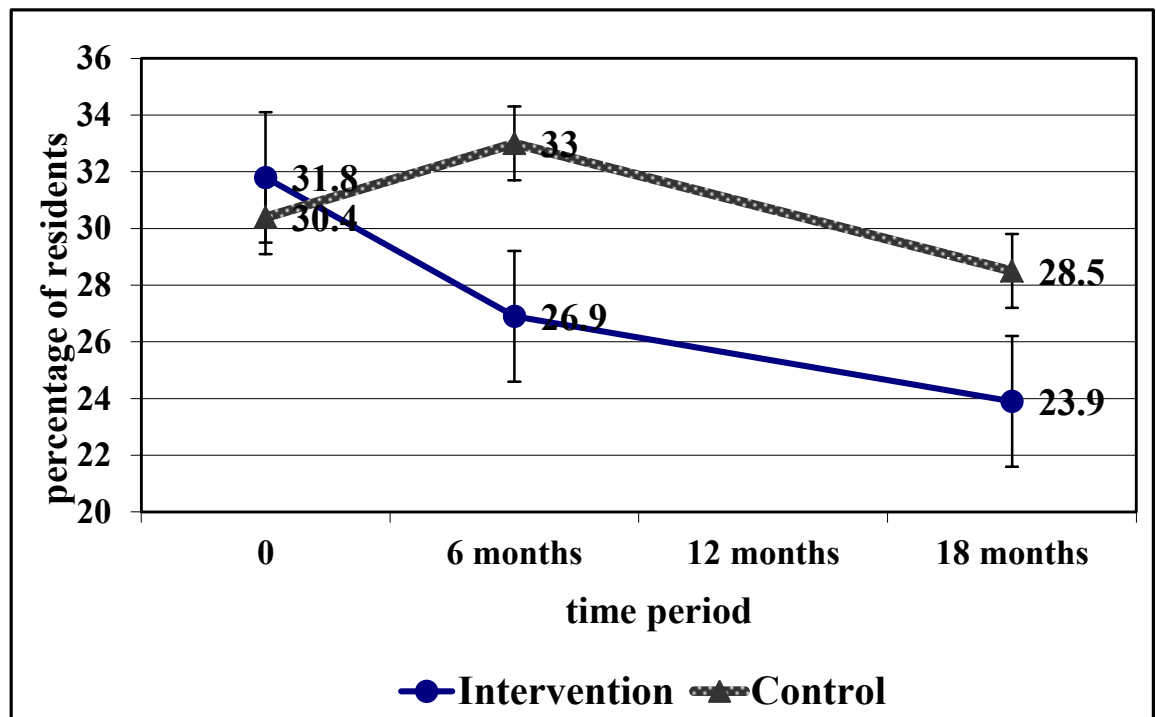
**Table 84: Summary of the dosage equivalents of residents taking psychotropic agents from baseline to follow-up (mean equivalents)**

Psychotropic	Intervention mg/day			Control mg/day		
	baseline t = 0	trial end t = 6	follow-up t = 18	baseline t = 0	trial end t = 6	follow-up t = 18
<b>Antipsychotics (Mean daily chlorpromazine equivalents)</b>	92.5	90.0	97.1	108.0	111.9	147
<b>Benzodiazepines (Mean daily diazepam equivalents)</b>	12.2	10.8	9.2	9.6	9.8	10.0

#### *25.6.2.1 The overall effect of RedUSE on benzodiazepine rates from baseline to follow-up*

Benzodiazepine prevalence decreased consistently over all time periods in intervention RACFs. (Fig 31). In contrast, mean prevalence increased in control facilities during the intervention but then decreased in the 12 months following the RedUSE trial. The two-way repeated measures ANOVA found no significant overall difference in benzodiazepine prevalence between RACF groups. There was, however, a significant decrease over time in benzodiazepine prevalence in each of the groups [ $F(2,23) = 6.2$ ;  $P < 0.005$ ]. A Fisher's PLSD post-hoc test revealed a significant decrease in overall benzodiazepine prevalence from baseline to the 18-month follow-up and in the 12 months following the RedUSE trial, but there was no significant difference in benzodiazepine prevalence during the trial itself. There was a significant interaction effect between trial group and time [ $F(2,23) = 3.8$ ;  $P < 0.05$ ]. Individual simple effects analysis of this interaction revealed that benzodiazepine prevalence was significantly reduced in intervention facilities when compared to control facilities at the end of the RedUSE trial [ $F(2,23) = 12.1$ ;  $P < 0.05$ ] but not 12 months after the trial, or the 18 months since RedUSE was initiated.

**Figure 31: Mean proportion of benzodiazepine use in intervention vs. control RACFs from baseline (time 0) to follow-up (time 18 months)**

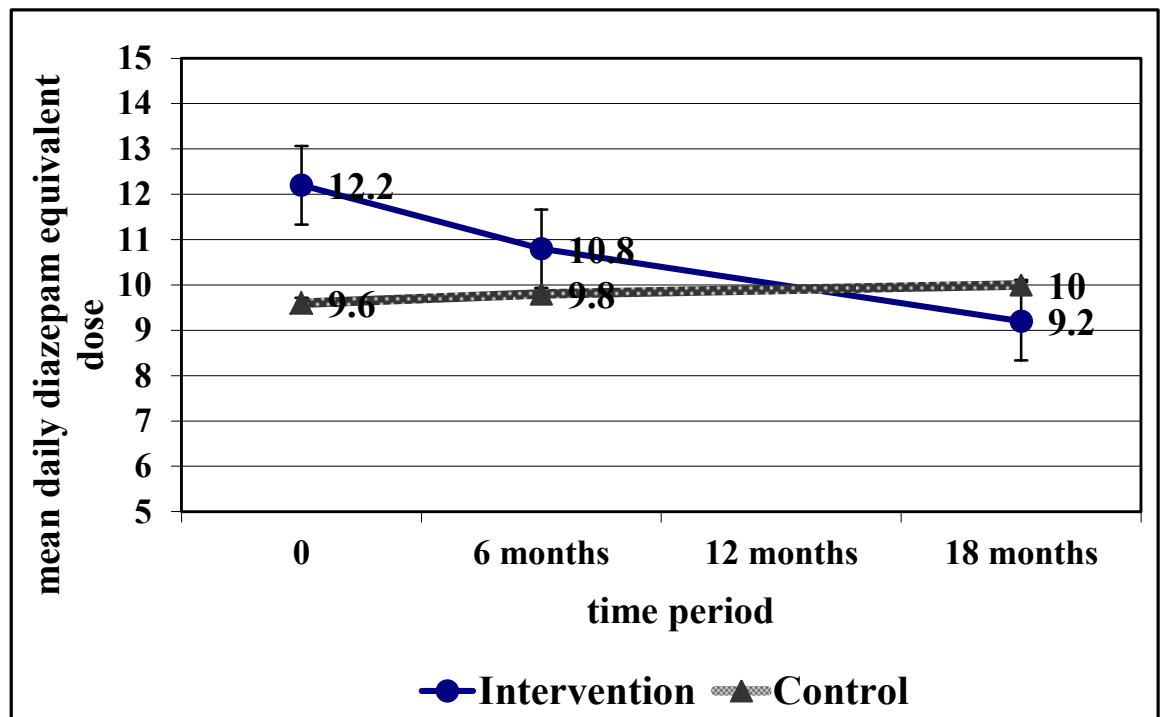


#### 25.6.2.2 The overall effect of RedUSe on daily diazepam equivalence from baseline to follow-up

The mean daily diazepam dose equivalence across the three time periods is illustrated in Figure 32. Mean daily diazepam equivalent dose values decreased consistently across all time periods in the intervention RACF group, whereas daily diazepam equivalence in the control facilities increased slightly over the same time periods. A two-way repeated measures ANOVA demonstrated no significant difference overall between RACF groups or across time; however, there was a significant interaction effect between trial group and time [ $F(2,23) = 4.7$ ;  $P < 0.02$ ]. This indicates that mean daily diazepam equivalences in the intervention and the control RACF groups changed differently over the three time periods. Individual simple effects analysis of this interaction revealed that daily diazepam equivalence was not significantly reduced in intervention facilities when compared to control facilities during the RedUSe trial or in the 12 months following the trial. However, over the 18 months since RedUSe was initiated the mean daily diazepam equivalence in intervention RACFs had reduced significantly in comparison to control RACFs [ $F(2,23) = 6.3$ ;  $P < 0.02$ ].



**Figure 32: Mean daily diazepam equivalent dose in intervention vs. control RACFs from baseline (time 0) to follow-up (time 18 months)**

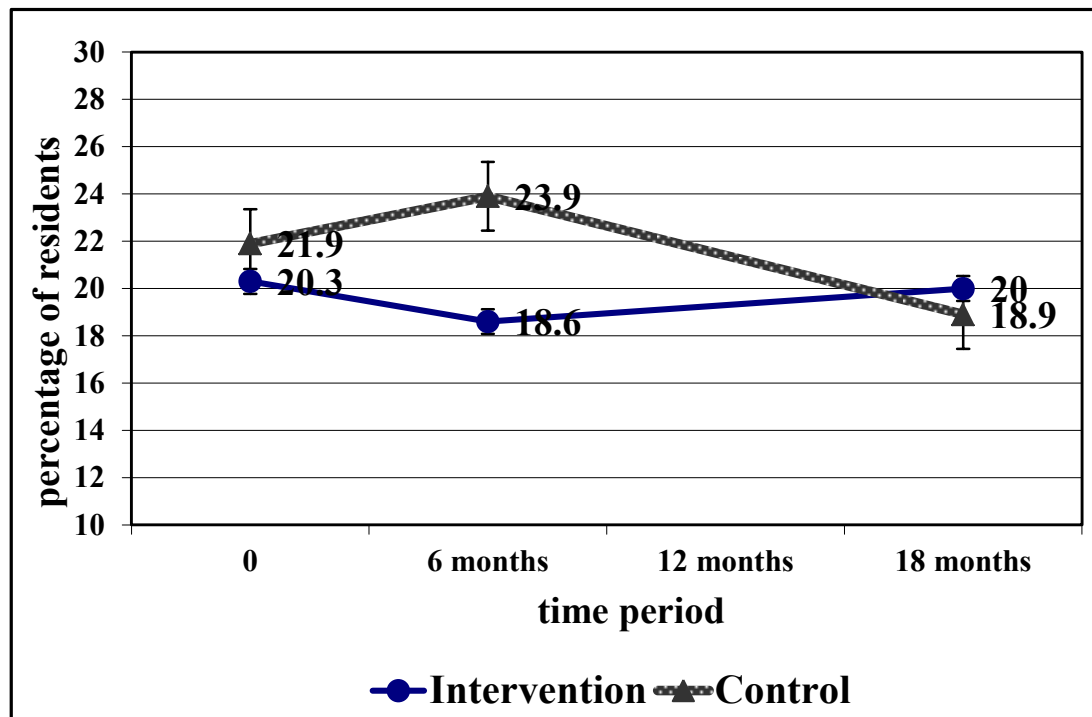


Overall, when comparing baseline to the 18-month follow-up, the prevalence of benzodiazepine use and mean daily diazepam equivalence in intervention RACFs had decreased by 25% and 24%, respectively. On the other hand, neither benzodiazepine prevalence nor mean daily diazepam equivalence had altered significantly in control facilities.

#### 25.6.2.3 The overall effect of RedUSE on antipsychotic rates from baseline to follow-up

Antipsychotic prevalence across the three data collection points is shown at Figure 33. Following an initial decrease in usage in the intervention RACFs throughout the RedUSE trial, the antipsychotic prevalence rate returned to baseline level at the 18-month follow-up measure. In control RACFs antipsychotic use increased throughout the trial period but then decreased markedly during the 12 months following the RedUSE project. The two-way repeated measures ANOVA revealed no significant overall differences between trial groups or across time; however, there was a significant interaction effect on antipsychotic prevalence between RACF group and time [ $F(2,23) = 3.9$ ;  $P < 0.05$ ]. Individual simple effects analysis of this interaction revealed that antipsychotic prevalence was significantly reduced in intervention facilities when compared to control facilities during the RedUSE trial [ $F(2,23) = 5.0$ ;  $P < 0.05$ ]. Conversely, antipsychotic prevalence was significantly reduced in control facilities when compared to intervention RACFs in the 12 months following the RedUSE project [ $F(2,23) = 6.8$ ;  $P < 0.02$ ].

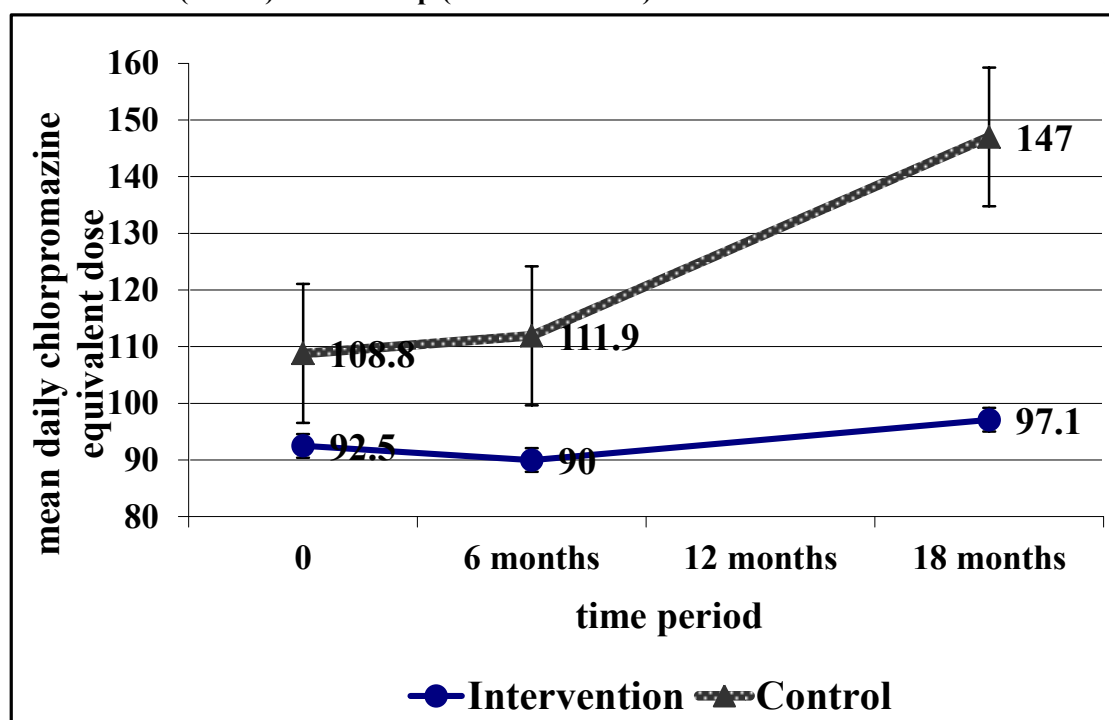
**Figure 33: Mean proportion of antipsychotic use in intervention vs. control RACFs from baseline (time 0) to follow-up (time 18 months)**



#### 25.6.2.4 The overall effect of RedUSE on daily chlorpromazine equivalence from baseline to follow-up

The mean daily chlorpromazine equivalence in intervention and control RACFs across all time periods is shown in Figure 34. Intervention facility daily chlorpromazine equivalence remained relatively constant across all three data collection points. However, mean daily chlorpromazine equivalence in control RACFs rose sharply in the 12 months following the RedUSE project. A two-way repeated measures ANOVA demonstrated a significant difference between intervention and control RACF mean daily chlorpromazine equivalence values [ $F(2,23) = 7.9$ ;  $P = 0.01$ ], and a significant difference across time [ $F(2,23) = 4.2$ ;  $P < 0.05$ ]. A Fisher's PLSD post-hoc test revealed a significant increase in mean daily chlorpromazine equivalence between baseline and 18-month follow-up and in the 12 months following the RedUSE trial. The increase in mean daily chlorpromazine equivalence during the RedUSE trial was not significant. Finally, no interaction between RACF group and time was found, meaning that mean daily chlorpromazine equivalence in intervention and control RACF groups were not affected differently over time.

**Figure 34: Mean daily chlorpromazine equivalent dose in intervention vs. control RACFs from baseline (time 0) to follow-up (time 18 months)**



#### 25.6.2.5 General psychotropic use

An itemised listing of psychotropics used in intervention and control RACFs at the three time-point measures is provided as Table 85. Notably, total antidepressant use did not vary significantly in either RACF group at any time point during and after the RedUse trial. However, in the 12 months following the RedUse project, mirtazapine prevalence increased from 5% to 10% in control RACFs; coinciding with a 4% fall in hypnotic benzodiazepine use. The use of the sedating TCAs and mirtazapine remained constant throughout all time periods in intervention RACFs.

**Table 85: Number (%) of RACF residents taking psychotropic medication regularly in Intervention and Control facilities at Baseline (Aug/Sep 2008), Week 26 (Mar 2009) and Week 78 (Mar 2010)\***

	<i>Intervention nursing homes</i>			<i>Control nursing homes</i>		
	Baseline (n=891)	Week 26 (n=888)	Week 78 (n=863)	Baseline (n=684)	Week 26 (n=705)	Week 78 (n=715)
<b>Psychotropics</b>						
Any psychotropic	<b>553(62%)</b>	<b>527(59%)</b>	<b>528(61%)</b>	<b>427(62%)</b>	<b>461(65%)</b>	<b>427(60%)</b>
Antipsychotics	<b>186(21%)</b>	<b>172(19%)</b>	<b>179(21%)</b>	<b>153(22%)</b>	<b>163(23%)</b>	<b>133(19%)</b>
<u>Typical</u>	35 (4%)	20 (2%)	24 (3%)	56 (8%)	39 (6%)	25 (3%)
Haloperidol	29	15	20	46	32	20
Chlorpromazine	4	3	4	4	1	4
Trifluoperazine	0	0	0	4	6	1
<u>Atypical</u>	159 (18%)	159 (18%)	179 (21%)	133 (19%)	141 (20%)	136 (19%)
Risperidone	81	78	97	71	81	74
Olanzapine	65	65	68	50	44	36
Quetiapine	13	16	14	12	16	26
Anxiolytic/hypnotics	<b>290(33%)</b>	<b>245(28%)</b>	<b>203(24%)</b>	<b>209(31%)</b>	<b>229(32%)</b>	<b>203(28%)</b>
<u>Hypnotics</u>	176(20%)	131(15%)	114(13%)	137 (20%)	138 (20%)	115(16%)
Temazepam	168	122	106	113	119	99
Nitrazepam	8	9	8	24	18	16
<u>Z-drugs</u>	1	1	2	0	1	2
<u>Anxiolytics</u>	160 (18%)	148 (17%)	121 (14%)	144 (21%)	141 (20%)	139(19%)
Oxazepam	83	84	63	87	95	95
Diazepam	52	40	40	46	37	33
Alprazolam	21	20	14	10	9	11
Antidepressants	<b>355(40%)</b>	<b>352 (40%)</b>	<b>350(41%)</b>	<b>254 (37%)</b>	<b>275 (39%)</b>	<b>275(38%)</b>
<u>Tricyclics</u>	66 (7%)	59 (7%)	50 (6%)	79 (12%)	60 (9%)	61 (9%)
Amitriptyline	36	35	31	40	33	35
Doxepin	12	12	10	15	11	13
Imipramine	4	3	2	12	7	8
<u>SSRIs</u>	192 (22%)	204 (23%)	210 (24%)	180 (26%)	141(20%)	140 (20%)
Sertraline	95	97	96	73	59	64
Citalopam	49	54	53	37	32	26
Escitalopam	19	24	26	25	25	25
Fluvoxamine	15	14	11	15	11	9
Fluoxetine	13	12	22	13	9	16
<u>SNRIs &amp; Others</u>	117 (13%)	125 (14%)	117 (14%)	86 (13%)	86 (12%)	120 (17%)
Mirtazapine	73 (8%)	69 (8%)	75 (9%)	37 (5%)	35 (5%)	73 (10%)
Venlafaxine	31	36	20	37	37	40
Moclobemide	5	7	6	7	7	6
Cholinesterase Inhibitors	<b>19 (2%)</b>	<b>16 (2%)</b>	<b>22 (3%)</b>	<b>2 (0.3%)</b>	<b>3 (0.4%)</b>	<b>9 (1%)</b>
sodium valproate	43 (5%)	47(5%)	45 (5%)	39 (6%)	32 (5%)	46 (6%)
carbamazepine	14	13	14	6	5	10
pregabalin	3	3	6	0	0	3

\* NB. This listing does not include every psychotropic medication prescribed. Other agents used in low quantities were not listed individually but were included in overall psychotropic class tallies.

## **25.7 Discussion**

The results of this follow-up study strongly suggest that the RedUSE trial had a sustained effect on reducing both benzodiazepine prevalence and daily diazepam dose equivalence. One of the main effects was on the daily diazepam dose equivalence, which reached statistical significance in the 18-month measure. These findings indicate that not only were fewer RACF residents in the intervention prescribed benzodiazepines at the 18-month follow-up, but also that doses of benzodiazepines were lower and/or continued to be reduced. One of the main educational messages of the RedUSE project was to gradually reduce psychotropic doses with the aim of tapering off use so it is pleasing to see that a reduction in dosing was still occurring in the absence of active intervention strategies. Although overall benzodiazepine prevalence had declined slightly in control facilities since the start of the RedUSE project, the daily dose equivalence of diazepam increased slightly, a finding which suggests that limited attention was directed towards reducing benzodiazepine doses in control facilities.

During the RedUSE trial, antipsychotic prevalence was found to decrease significantly in intervention facilities; however, at the 18-month follow-up measure, antipsychotic use had not altered significantly from the baseline level. In a similar fashion, mean daily chlorpromazine doses in intervention RACFs decreased slightly during the intervention but then increased slightly over the follow-up period, suggesting that limited attention was paid to reducing antipsychotic doses in this period. These findings imply that the effect of the intervention on antipsychotic prescribing and dosing was not sustained, and that continued intervention strategies are needed to help RACFs maintain low rates of antipsychotic use or reduce antipsychotic use further.

There are several reasons to explain why the impact of RedUSE was sustained with benzodiazepine use but not with antipsychotic use. As outlined previously, in comparison to other areas of Australia and New Zealand, the prevalence of benzodiazepines is much higher in Tasmania, whereas the use of antipsychotics is lower than that found in other studies.<sup>623</sup> Although the educational sessions, guidelines and audit feedback strategies of the RedUSE project targeted both antipsychotic and benzodiazepine prescribing, there was always greater scope and capacity for reduction in benzodiazepine use than antipsychotic use.

The preferred treatment options to manage behavioural disturbance, anxiety and sleep disorders are non-pharmacological strategies.<sup>64,95,261</sup> It may be easier for RACFs to provide non-pharmacological strategies to manage sleep and anxiety, conditions treated by benzodiazepines, than it is to provide non-drug strategies to treat behavioural disturbances of dementia. An intervention involving 12 U.K. RACFs successfully trialled the use of non-pharmacological strategies delivered by trained clinicians (a psychologist, occupational therapist or nurse) for two days a week for 10 months.<sup>209</sup> Although antipsychotic prevalence dropped by half in

intervention RACFs when compared to control RACFs in this study, the majority of Australian RACFs would not have the resources to provide the same level of psychosocial support to enable as effective provision of non-pharmacological strategies.<sup>209</sup>

In the year following the RedUSE trial, control RACF benzodiazepine and antipsychotic prevalence measures were found to decline, with antipsychotic use declining significantly. It is hypothesised that this reduction is primarily due to a 'catch-up' effect. After the RedUSE trial was completed, reports on findings were distributed to all participant facilities and there was also considerable media attention directed towards the beneficial results of the trial. Several of the directors of nursing at the control RACFs requested the educational materials from RedUSE for use in their RACFs. Another possible contributor to the decline in antipsychotic use in control facilities was that a national educational program through NPS targeted at ensuring appropriate RACF antipsychotic use was delivered to the Launceston area mid-2009.<sup>244</sup> To our knowledge, this program was not delivered in the Hobart area, the locality of the intervention RACFs.

Several researchers have suggested that when antipsychotic and benzodiazepines are reduced other agents may be prescribed to produce substitute effects.<sup>581,585</sup> For this reason we evaluated the follow-up impact of the project on antidepressant prevalence as some of the antidepressant agents can be used for their sedating properties, for example, mirtazapine and TCAs, such as amitriptyline and doxepin.<sup>14</sup> Substitute prescribing of alternate agents in place of antipsychotics and benzodiazepines did not appear to occur in intervention facilities as antidepressant use was consistent throughout the trial and follow-up period. On the other hand, mirtazapine use doubled in control RACFs at the same time that hypnotic benzodiazepine prevalence decreased, suggesting that this antidepressant was substituted as an alternative to benzodiazepine treatment for its hypnotic effect. It should be recognised that mirtazapine is not licensed for use as a hypnotic agent and it should only be used when there are concomitant symptoms of depression.<sup>360</sup>

## **25.8 Strengths and limitations**

One of the strengths of this follow-up study is that all RACFs that were involved in the original RedUSE trial were re-recruited, meaning that the psychotropic data from the same facilities could be compared over time. As a consequence, this follow-up study provided an accurate reflection of psychotropic use in the 25 sample RACFs across the whole 18-month period; during and after an intervention project. A limitation of the study is that it is difficult to determine if the variations in dose equivalence found in the RACFs were due to different antipsychotic or benzodiazepine medications with varying equivalences being prescribed or whether variations to existing medication doses were made instead. For example, in the control

facilities there was a notable increase in the number of residents prescribed high doses of quetiapine in the twelve months following the RedUSE project, which may explain the marked elevation in mean chlorpromazine equivalence in this RACF group.

## **25.9 Conclusion**

In the twelve months after the RedUSE project, benzodiazepine prevalence and mean daily diazepam equivalence continued to decline in intervention RACFs, resulting in an overall reduction of about 25% from baseline in both values. However, the effect of the RedUSE intervention on antipsychotic prevalence and dosage was not sustained.

## CHAPTER TWENTY SIX: GENERAL CONCLUSION

### ROLES FOR PHARMACISTS IN IMPROVING THE QUALITY USE OF PSYCHOTROPIC MEDICINES IN RESIDENTIAL AGED CARE FACILITIES

#### **26.1 General Conclusion**

The majority of residents in RACFs have dementia and with it, the behavioural and psychological symptoms that often accompany the disease. Many residents also suffer from the mental health conditions of anxiety and sleep disturbance. Antipsychotic and benzodiazepine medications are often administered to manage these common old age mental health disorders despite offering modest benefit and significant adverse effects. Many researchers around the world have shown that psychotropic medication is commonly prescribed in RACFs to manage the behavioural and psychological symptoms of older residents. This high rate of prescribing occurs despite a broad base of evidence supporting the use of non-pharmacological strategies to manage these conditions and ‘good practice’ advice from government, professional organisations and academia which stresses judicious use, review and regular trials of dose reduction.

The first aim of this project was to assess the pattern of use of psychotropic medications in Tasmanian RACFs. This was achieved by performing a large cross-sectional study in half the RACF residents in the state. We found the rate of benzodiazepine prescribing to be three times higher than rates recorded in Central Sydney and Hawkes Bay, New Zealand at the same time. The use of antipsychotic medications was slightly lower than rates recorded in Sydney and New Zealand, suggesting that benzodiazepines may be frequently used to manage BPSD. Many of the psychotropic agents used in residents were also classified as potentially inappropriate when assessed by U.S. standards, with about a third of benzodiazepine doses exceeding recommended geriatric doses and over 10% of antipsychotic doses categorised as potentially inappropriate.

The majority of guidelines recommend that antipsychotic and benzodiazepine agents are reviewed regularly and dosages tapered down with the view to eventual cessation. The second study aimed to evaluate if regular review was occurring by evaluating the extent of psychotropic dosage variation over a 12- month period. It was found that nearly two thirds of antipsychotic and benzodiazepine agents and doses remained unaltered. One relevant finding was that psychotropic agents were not frequently initiated in residents. The main reason for the high prevalence rate of antipsychotics and benzodiazepines appeared to be related to the fact that once residents started these medications they stayed on them for extended periods of time. Thus one way to reduce the use of psychotropic medication was to implement an effective system which promoted the review and dose tapering of these agents.



Yet, a medication review program already existed in Australian RACFs. All of the residents audited in the first two studies of this thesis had at least one pharmacist-provided RMMR. Pharmacists coordinating these services were also funded to provide QUM services to facilities, including audit, educational sessions and general pharmaceutical advice. Why weren't these pharmacy-led services providing a significant impact on psychotropic rates of use or review? Did pharmacists have a role to play when it came to ensuring quality use of antipsychotic and benzodiazepine medications? Other important questions to consider were why were these medications used so frequently, and who exactly was influencing their prescribing? What were the barriers to their review? What exactly were the roles of GPs, nurse and pharmacists relating to psychotropic medication?

To answer these key research questions and to gain increased understanding of the determinants of psychotropic prescribing and review, a qualitative study was performed in which key health providers were interviewed, along with relatives of residents who were legally responsible for their medical treatment. Psychotropic medications were mainly prescribed to provide comfort to distressed residents in the belief that using them would increase the residents' quality of life. Nursing staff were found to be highly influential when these medications were prescribed. However, there was uncertainty among health professionals over what agents to use, what dose to prescribe, when they should be reviewed and whose role it was to monitor them. Health practitioners were reluctant to trial dosage reductions because they were concerned mental health symptoms would re-emerge. Many GPs sought minimal involvement due to time and financial constraints. Relatives were often left in the dark when these medications were prescribed due to a lack of knowledge and a sense that they were happy to hand over prescribing responsibility to the 'experts'. The role of pharmacists regarding psychotropic prescribing and review appeared to be minimal.

However, the contribution of pharmacists is highly valued in RACFs, by nursing staff in particular. One of the main barriers to pharmacists promoting the quality use of psychotropic agents was that many of them did not have sufficient knowledge about the use of psychotropic medication to treat old age mental health conditions. Accredited pharmacists performing RMMRs had also encountered marked resistance from GPs and nurses when they made recommendations to reduce psychotropic medications so were understandably reluctant to do so. When pharmacists were asked whether QUM activities were directed towards improving the use of psychotropic medication, only one out of 15 pharmacies had performed an audit of psychotropic use for their RACF in a year of data collection. None had provided any training on their appropriate use.

The Reducing Sedatives (RedUSE) project was designed, trialled and evaluated with the specific aim of equipping community pharmacists with the necessary knowledge and QUM

strategies to be able to take on the important role of promoting appropriate use of antipsychotic and benzodiazepine medication in RACFs. When a group of ten pharmacists were educated about psychotropic medication and armed with a set of strategies, including education for nursing staff, an audit program and the sedative review process that was designed to include nursing staff, they were able to effectively facilitate a reduction in benzodiazepine and antipsychotic rates of use in many of the RACFs.

The reduction in psychotropic use during the six months of the RedUSE project was moderate, but significant; however, the rates of benzodiazepine use declined more than the antipsychotic rate. Post-trial evaluation showed that the effect of the RedUSE trial on benzodiazepine medication was sustained, with doses continuing to be reduced during the year after the trial was completed. To the contrary, rates of antipsychotic use returned to pre-trial levels a year after the RedUSE project and mean doses in facilities remained unaltered. Although the RedUSE project's priority was always on reducing benzodiazepine use, other interventions to reduce psychotropic use in RACFs have also reported a greater impact on benzodiazepine use when compared to antipsychotic use. It appears that continued educational interventions and other QUM services are required to impact the use of antipsychotic medication.

A post-analysis conducted after the RedUSE project aimed to assess the effect of reducing psychotropic medication on the clinical outcome measures of fall rate and incidence of challenging behaviour. Although the quality of outcome data was not robust, no effect was observed on falls rates by reducing either benzodiazepine or antipsychotic use. However, the number of challenging behaviours significantly decreased when antipsychotic use was reduced. Both of these findings have previously been observed in other intervention and psychotropic withdrawal studies where clinical outcome data has been analysed.

The main limitation of the project involved GP participation. As prescribers, GP involvement and support is crucial if medication doses are to be reduced. Like with their RACF participation generally, GPs sought limited involvement in the RedUSE project. If greater collaboration could be achieved between the key three professionals, pharmacists, nurses and GPs, it is highly possible that a greater reduction in psychotropic prescribing could be realised.

The RedUSE project effectively demonstrated that there is an important role for pharmacists in ensuring quality use of psychotropic medication in the residential care setting providing they are equipped with the necessary background knowledge and a coordinated toolkit of easy-to-deliver QUM strategies.

## **26.2 Future directions:**

The future directions of the RedUSe project include:

### **26.2.1 The refinement and expansion of the ‘RedUSe’ project**

The positive findings of the RedUSe project may have been impacted by the high baseline rate of benzodiazepine prescribing in Tasmania or influenced by other factors such as unsolicited media attention. Further research is necessary to assess the impact of the project’s strategies on antipsychotic and benzodiazepine use in RACFs in other areas of the country.

### **26.2.2 The investigation of the long-term clinical outcomes and health economic benefits from reducing inappropriate sedative use in aged care.**

Additional research funding should be allocated to provide direct evidence of the clinical benefits to residents of reducing the use of sedative medications in RACFs; for example, the inclusion of standardised falls, behaviour, cognition and quality of life measures. These outcome measures were not factored into the original RedUSe proposal and would strengthen the project considerably, as well as provide innovative evidence of the impact of sedative reduction on residents.

The original RedUSe project did not incorporate a detailed cost effectiveness analysis in its design. Such professional health economist input incorporating the impact on quality of life measures, falls and other clinical outcome data, would enable assessment of the financial impact of reducing psychotropic medication in RACFs to the Australian Health System.

### **26.2.3 Detailed investigation regarding the facilitators and barriers to incorporating nursing involvement into the medication review process.**

Nursing staff in RACFs appear to be a key influence when sedative medications are initiated, used and reviewed. Involving nursing staff to a greater degree in discussions about resident use of medicines has the potential to improve the outcomes of the RMMR process. Therefore, further research should be undertaken with the overall aim of promoting the involvement of RACF nursing staff in medication review processes to a much greater degree.

## **26.3 Roles for pharmacists to improve the quality use of psychotropic medicines in RACFs**

The RedUSe project resulted in a significant decrease in several important parameters, including antipsychotic and benzodiazepine prevalence rates and multiple psychotropic agent use in RACFs. Further, the project markedly and significantly increased the number of dosage reductions of antipsychotic and benzodiazepine medications. It is important to appreciate that

community pharmacists were the health professional group driving these important outcomes through enhanced knowledge of the issues and the use of a coordinated set of QUM services specifically designed to promote quality use of psychotropic medication.

One of the main intentions of the current RMMR program and associated QUM services was to promote the quality use of psychotropic medication in RACFs. These practice initiatives are currently funded by the Federal government and are actively promoted by the Department of Health and Ageing, professional pharmacy organisations as well as being firmly underpinned by policies such as the 'National Medicines Policy' and the 'Standards for Aged Care Facilities'. Yet, in spite of these important practice initiatives underpinned by both policy and professional body support, the use of psychotropic medications has remained elevated in RACFs over the past 30 years and the rate of review of these agents, as indicated by the minimal rate of dosage reduction and cessation, is low. Qualitative and QUM audit data, conducted as important pre-intervention research, highlighted the fact that pharmacists were reluctant to recommend dose reductions of these agents in RMMRs, mainly due to marked resistance to alter them. It is also notable that QUM services directed towards ensuring appropriate psychotropic use were rarely implemented.

However, when community pharmacists were equipped with the knowledge, skills and a co-ordinated set of QUM services, as in the RedUSE project, they effectively demonstrated that there is an important role for pharmacists in ensuring quality use of psychotropic medication in the residential care setting. This project has also emphasised the importance of community pharmacists working effectively with other members of the health care team to achieve beneficial reductions in inappropriate medication use.

In qualitative data contained within this thesis community pharmacists were shown to be highly valued by the majority of the RACF nursing staff and GPs interviewed; yet pharmacists do not appear to be achieving their full potential as important promoters of QUM in RACFs as intended. Many of the DONS in RACFs surveyed were simply not offered structured QUM services such as educational sessions or medication audits by their community pharmacists. Further, many RACFs surveyed before the RedUSE project did not hold MACs or conduct case conferences involving pharmacists. Changes to the way QUM services are funded and audited in the new fifth community pharmacy agreement may address this deficiency to some degree but community pharmacists also need to take full advantage of the policy and professional support that is available by providing a greater range and quality of QUM services to RACFs. Professional organisations such as the PSA, Pharmacy Guild, the AACP and the NPS could support community pharmacist more in this regard by offering professional CPE in areas relevant to RACFs and by developing and providing coordinated sets of nurse educational, audit and QUM service materials, similar to the materials that were developed in the RedUSE project.

Finally, community pharmacists must also seek ways they can work more collaboratively with nursing staff, the growing number of nurse practitioners, GPs and geriatricians in the RACF setting, for ultimately, the greatest improvements in quality use of psychotropic medication were observed when nurses, GPs and pharmacists communicated effectively and worked together with the combined aim of resident-focused care.

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## Neuropsychiatric Inventory Questionnaire.

This tool provides a reliable assessment of behaviours commonly observed in patients with dementia.

*Adapted with permission from Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. J Neuropsychiatry Clin Neurosci 2000;12:233–9.*

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Name of patient: \_\_\_\_\_ Date: \_\_\_\_\_

Informant: Spouse: \_\_\_\_\_ Child: \_\_\_\_\_ Other: \_\_\_\_\_

Please answer the following questions based on changes that have occurred since the patient first began to experience memory problems.

Circle "yes" only if the symptom has been present in the *past month*. Otherwise, circle "no".

For each item marked "yes":

Rate the *severity* of the symptom (how it affects the patient):

1 = Mild (noticeable, but not a significant change)

2 = Moderate (significant, but not a dramatic change)

3 = Severe (very marked or prominent; a dramatic change)

Rate the *distress* you experience because of that symptom (how it affects you):

0 = Not distressing at all

1 = Minimal (slightly distressing, not a problem to cope with)

2 = Mild (not very distressing, generally easy to cope with)

3 = Moderate (fairly distressing, not always easy to cope with)

4 = Severe (very distressing, difficult to cope with)

5 = Extreme or very severe (extremely distressing, unable to cope with)

Please answer each question honestly and carefully. Ask for assistance if you are not sure how to answer any question.

<b>Delusions</b>	Does the patient believe that others are stealing from him or her, or planning to harm him or her in some way?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Hallucinations</b>	Does the patient act as if he or she hears voices? Does he or she talk to people who are not there?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Agitation or aggression</b>	Is the patient stubborn and resistive to help from others?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Depression or dysphoria</b>	Does the patient act as if he or she is sad or in low spirits? Does he or she cry?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Anxiety</b>	Does the patient become upset when separated from you? Does he or she have any other signs of nervousness, such as shortness of breath, sighing, being unable to relax, or feeling excessively tense?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Elation or euphoria</b>	Does the patient appear to feel too good or act excessively happy?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Apathy or indifference</b>	Does the patient seem less interested in his or her usual activities and in the activities and plans of others?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Disinhibition</b>	Does the patient seem to act impulsively? For example, does the patient talk to strangers as if he or she knows them, or does the patient say things that may hurt people's feelings?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Irritability or lability</b>	Is the patient impatient and cranky? Does he or she have difficulty coping with delays or waiting for planned activities?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Motor disturbance</b>	Does the patient engage in repetitive activities, such as pacing around the house, handling buttons, wrapping string, or doing other things repeatedly?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Nighttime behaviors</b>	Does the patient awaken you during the night, rise too early in the morning, or take excessive naps during the day?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5
<b>Appetite and eating</b>	Has the patient lost or gained weight, or had a change in the food he or she likes?
Yes    No	Severity: 1    2    3    Distress: 0    1    2    3    4    5

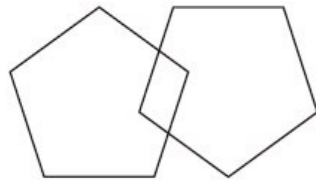


## The Mini-Mental State Exam

Patient \_\_\_\_\_ Examiner \_\_\_\_\_ Date \_\_\_\_\_

Maximum      Score

- |   |     |   |
|---|-----|---|
|   |     | <b>Orientation</b>  |
| 5 | ( ) | What is the (year) (season) (date) (day) (month)?   |
| 5 | ( ) | Where are we (state) (country) (town) (hospital) (floor)?   |
|   |     | <b>Registration</b>   |
| 3 | ( ) | Name 3 objects: 1 second to say each. Then ask the patient<br>all 3 after you have said them. Give 1 point for each correct answer.<br>Then repeat them until he/she learns all 3. Count trials and record.<br>Trials _____ |
|   |     | <b>Attention and Calculation</b>  |
| 5 | ( ) | Serial 7's. 1 point for each correct answer. Stop after 5 answers.<br>Alternatively spell "world" backward.   |
|   |     | <b>Recall</b>   |
| 3 | ( ) | Ask for the 3 objects repeated above. Give 1 point for each correct answer.   |
|   |     | <b>Language</b>   |
| 2 | ( ) | Name a pencil and watch.  |
| 1 | ( ) | Repeat the following "No ifs, ands, or buts"  |
| 3 | ( ) | Follow a 3-stage command:<br>"Take a paper in your hand, fold it in half, and put it on the floor."   |
| 1 | ( ) | Read and obey the following: CLOSE YOUR EYES  |
| 1 | ( ) | Write a sentence.   |
| 1 | ( ) | Copy the design shown.  |



\_\_\_\_\_ Total Score  
ASSESS level of consciousness along a continuum \_\_\_\_\_  
Alert Drowsy Stupor Coma

**GERIATRIC DEPRESSION RATING SCALE**Brink et al., 1982; Yesavage et al., 1983 - SHORT version - Sheik et al., 1986

(to be completed by a trained clinician)

DATE:  TIME (24hr): 

Choose the best answer for how you have felt over the past week:

**Yes / No**

- [ ☐ ] [ ☐ ] 1. Are you basically satisfied with your life?
- [ ☐ ] [ ☐ ] 2. Have you dropped many of your activities and interests?
- [ ☐ ] [ ☐ ] 3. Do you feel that your life is empty?
- [ ☐ ] [ ☐ ] 4. Do you often get bored?
- [ ☐ ] [ ☐ ] 5. Are you in good spirits most of the time?
- [ ☐ ] [ ☐ ] 6. Are you afraid that something bad is going to happen to you?
- [ ☐ ] [ ☐ ] 7. Do you feel happy most of the time?
- [ ☐ ] [ ☐ ] 8. Do you often feel helpless?
- [ ☐ ] [ ☐ ] 9. Do you prefer to stay at home, rather than going out and doing new things?
- [ ☐ ] [ ☐ ] 10. Do you feel you have more problems with memory than most?
- [ ☐ ] [ ☐ ] 11. Do you think it is wonderful to be alive now
- [ ☐ ] [ ☐ ] 12. Do you feel pretty worthless the way you are now
- [ ☐ ] [ ☐ ] 13. Do you feel full of energy?
- [ ☐ ] [ ☐ ] 14. Do you feel that your situation is hopeless?
- [ ☐ ] [ ☐ ] 15. Do you think that most people are better off than you are?

TOTAL GDS: 

(GDS maximum score = 15)

- 0 - 4 normal, depending on age, education, complaints
- 5 - 8 mild
- 8 - 11 moderate
- 12 - 15 severe

# Cohen-Mansfield Agitation Inventory (CMAI)

**Instructions:** For each of the behaviors below, check the rating that indicates the average frequency of occurrence over the last 2 weeks.

Behavior	Never 1	Less Than Once a Week 2	Once or Twice a Week 3	Several Times a Week 4	Once or Twice a Day 5	Several Times a Day 6	Several Times an Hour 7
1. Hitting (including self) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Kicking .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Grabbing onto people .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Pushing .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Throwing things .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Biting .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Scratching .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Spitting .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Hurt self or others .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Tearing things or destroying property .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Making physical sexual advances .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Paces, aimless wandering .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Inappropriate dress or disrobing .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Trying to get to a different place. .	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Intentional falling .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Eating/drinking inappropriate substances .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Handling things inappropriately .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Hiding things .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Hoarding things .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Performing repetitious mannerisms .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. General restlessness .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Screaming .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Making verbal sexual advances ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Cursing or verbal aggression .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Repetitive sentences or questions .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Strange noises (weird laughter or crying) .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Complaining .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Negativism .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Constant unwarranted request for attention or help .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Name of Rater: \_\_\_\_\_

Name of Primary Caregiver/Informant: \_\_\_\_\_

Note: This is the nursing-home, long version of the Cohen-Mansfield Agitation Inventory. For definitions of the behaviors, administration, scoring information, and other versions, please consult the manual.



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5 March 2008

***‘The quality use of medicines to manage behavioural and psychological symptoms in residential care.’***

Dear Sr .....

We would like to invite your Residential Care Facility (RCF) to participate in a research project, conducted by a PhD candidate; Juanita Westbury, at the Tasmanian School of Pharmacy.

Briefly, this project aims to examine factors involved with the management of challenging behaviours such as wandering, apathy, agitation, sleep disturbance and delusions. These symptoms are often the reason for admission into RCFs and are also a leading cause of stress for residents, families and nursing staff. The effective management of challenging behaviour will become increasingly important as the dementia rate rises due to our ageing population.

Psychotropic medications are often prescribed in RCFs to manage behaviours. An aim of this study is to examine the factors that influence the prescribing of these medications. To achieve this, we plan to interview health professionals namely GPs, nurses and pharmacists. We also hope to talk to enduring guardians/persons’ responsible of residents. Through the use of semi-structured interviews it is intended to record examples and explanations to increase our understanding of how challenging behaviours are managed in RCFs and learn more about why medicines are chosen and utilised for this indication. This project has received ethical approval from the Human Research Ethics Committee (Tasmania) Network, which is constituted under the National Health & Medical Research Council.

**Your participation will involve allowing two of your nursing staff members to be interviewed and providing the details of several GPs and the supply pharmacy that regularly attend the RCF. We will also request that you identify and contact several enduring guardians/persons’ responsible of residents displaying behaviour that challenges and provide them with information about the research and an invitation to participate in an interview. All interviewees will be offered a gift voucher to the value of \$100 to compensate for their time.**

We would like to stress that all personal information will be removed from the interviews in the course of the transcription so that it will not be possible to identify individuals or the RCF from any written documents, reports or publications produced during the research. Further information about this research is provided in the information sheet attached. I will contact you next week to discuss your thoughts on participating. If you have any questions about the study, please contact me.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Juanita Westbury'.

Juanita Westbury  
PhD candidate  
School of Pharmacy  
University of Tasmania

A handwritten signature in black ink, appearing to read 'Gregory Peterson'.

Professor Gregory Peterson  
Professor and Chief Investigator  
School of Pharmacy  
University of Tasmania



## ***‘The quality use of medicines to manage behavioural and psychological symptoms in residential care’***

### **INVITATION AND INFORMATION SHEET FOR PHARMACISTS**

You are invited to take part in a research project being conducted through the School of Pharmacy and the School of Nursing and Midwifery at the University of Tasmania entitled ‘The quality use of medicines to manage behavioural and psychological symptoms in residential care’. This information sheet contains details about the research project, the researchers, and why we have invited you to take part. It will explain to you all the procedures involved in the project so you can decide whether or not to take part.

#### **What is this project about?**

Many residents in aged care facilities will display challenging behaviours at some stage such as wandering, aggression, sleeping disturbance and calling out. These behavioural and psychological symptoms are often a leading cause of stress for residents, families and nursing staff.

The management of some challenging behaviours presented by residents is complex. We know that, in some cases, medications are prescribed to manage these types of symptoms. This study aims to examine, in depth, how behavioural and psychiatric symptoms are managed in residential care facilities. The study investigators are also interested in exploring under which circumstances medications are prescribed and establishing the roles of nursing staff, the GP, pharmacist and the resident’s family when these medications are chosen and utilised.

#### **Who are the researchers?**

Juanita Westbury, a community pharmacist, is performing this study as part of a Doctorate at the University of Tasmania. The results of this study will form a thesis to be submitted for her PhD. The researcher and research project are being supervised by Professor Gregory Peterson and Dr Shane Jackson from the University of Tasmania, and Professor Andrew Robinson from the School of Nursing and Midwifery at the University of Tasmania.

#### **Why have I been invited to take part in this research?**

You are invited to be involved because you provide pharmacy services to a residential care facility that has elected to take part in this research. We are seeking to interview a Pharmacist associated with each aged care facility. By being involved in this study you will be providing valuable information and viewpoints about the management of challenging behaviour in residents. This information will be used in order to better understand the factors behind management of psychiatric and behavioural symptoms.

#### **What would I need to do if I took part?**

If you agree to be part of this research, you will participate in an interview at a place convenient for you, where you will talk one-on-one with a researcher about your experiences and opinions about the management of challenging behaviours in residents. The researcher will ask general questions to encourage you to contribute your thoughts and ideas. A tape recorder will be used to record the discussion so that it can be typed up later.



### **Are there any risks or discomforts to me?**

Some people find it a little embarrassing to talk openly to a researcher, however, evidence shows that most people enjoy participating in this type of research because of the opportunity to share their experiences and opinions. The researcher will ask general questions and it is then up to you if you want to say anything. We would encourage you to participate as much as possible because we are interested in your thoughts and ideas. **A gift voucher for \$100 will be offered to each participant to compensate for their time.**

### **Will I be identifiable in the information collected?**

You will not be able to be identified by being involved in this study. No names will be used in the collection of the information and no information that could identify you individually will be published. We make sure you remain anonymous by using a code number instead of your name to identify any information you provide us with. In any reports or publications arising from this study, it is predominantly the combined results of all who participate that will be published. Although some verbatim quotes might be reported to illustrate the findings, they will be edited to prevent identification of the participant or the residential care facility involved.

### **How private is the information that I give?**

The researcher will treat all comments from each interviewee as confidential. During the course of the study, information from interviews will be stored on a password-protected computer at the School of Pharmacy in the University of Tasmania. Printed information will be stored in the locked filing cabinet for a period of five years following the study and then destroyed by shredding.

### **Can I withdraw from the research if I wish?**

Your participation in this study is entirely voluntary. You may withdraw from the study at any time without giving a reason. Refusing to participate in this research or agreeing to participate and then withdrawing will not affect you in any way.

### **Has this research been approved by an ethics committee?**

This project has received ethical approval from the Human Research Ethics Committee (Tasmania) Network, which is constituted under the National Health & Medical Research Council. If you have any concerns of an ethical nature or complaints about the manner in which the project is conducted, you may contact the Executive Officer of the Tasmanian Human Research Ethics Committee (Tasmania) Network on 62267479 or [human.ethics@utas.edu.au](mailto:human.ethics@utas.edu.au). You will need to quote ethics reference number H9774.

### **Who do I need to contact if I have any questions about the research?**

Information regarding this study can be obtained from Mrs Juanita Westbury: Phone: 6226 1966

Email: [Juanita.Westbury@utas.edu.au](mailto:Juanita.Westbury@utas.edu.au)

### **Consent form**

If you are willing to be interviewed, we ask that you sign the attached consent form and return it to the School of Pharmacy in the enclosed reply-paid envelope. You will be given a copy of the information sheet and statement of informed consent to keep. We thank you for taking the time to read this information sheet and hope that you will be willing to participate in this study.



Professor Greg Peterson, Chief Investigator



Juanita Westbury, PhD candidate & Researcher

***“The quality use of medicines to manage behavioural and psychological symptoms in residential care”.***

(N.B The schedule that follows is for a semi-structured interview, thus, the ordering of the questions will vary according to the way the interview evolves. Other questions not listed in this schedule may be asked to expand a topic if/as it emerges in the interview)

**Nursing staff Interview Schedule**

*For this study, I would like to examine some of the issues surrounding the management of challenging behaviour in residential care facilities. I am hoping to hear the experiences and opinions of nursing staff around some of the issues found in this patient group, in this setting.*

*To start with, do you mind if I ask you a few questions about working in the residential care environment?*

1. Can I ask how long you have been working at the ..... residential care facility?
2. How long have you worked in aged care?
3. How did you come to work in this area?
4. Moving onto the management of challenging behaviours and psychiatric symptoms, do many of the residents you care for exhibit these symptoms? What proportion would you estimate have these sort of issues?
5. How do you find caring for residents with challenging behaviours such as calling out or wandering?
6. For the next few questions, I would like to ask you to recall a recent case of a resident where there were issues concerning the management of behaviour? Could you describe the behaviour for me?
7. Can I ask how you dealt with the problem behaviour?
8. Did you involve the resident's GP? Why/why not?
9. How involved do you think the GPs want to be in the management of challenging behaviour ?
10. Do you ever encounter difficulties in contacting and getting a doctor to visit the facility? Would you have an example of this?
11. What are your thoughts on the use of medications to control behaviours?
12. In your experience, what medicines are normally prescribed for this indication?
13. How effective do you think these medicines are?
14. What training has been provided for you on the use of medicines for residents with challenging behaviours?

15. How would you rate this training? Do you think that the training prepares you adequately for working with and managing residents displaying challenging behaviour?
16. Are there any guidelines that you refer to when administering or checking a dose of a medication used in the management of challenging behaviour?
17. Have you encountered any side effects when antipsychotics such as Serenace, Zyprexa or Risperidal?
18. Could you describe these?
19. We know that benzodiazepines such as temazepam and oxazepam are sometimes prescribed for the management of some behaviours, and for the treatment of sleep disturbance. What are your thoughts on the use of benzodiazepines in this patient group?
20. How long do you feel that residents should be taking medications to control their behaviour?
21. Would the resident's family be contacted before/when these types of medications are prescribed?
22. How involved do you feel most relatives want to be in these sort of situations?
23. How involved do you think they should be?
24. Do relatives ever request that you do something to manage behaviours? Would you have an example?
25. What is your experience with multi-case conferences in the RCF about the management of patients? Did you find it beneficial?
26. What are your thoughts about non-drug treatment of some of these challenging behaviours? Distraction techniques, providing music or modifying the environment, for instance?
27. Medication reviews are routinely performed by pharmacists in this facility. Do you refer to the reviews written by the pharmacists? How useful do you find the reviews?
28. Would you ever consult the pharmacist /pharmacy about use of medications for challenging behaviour? If not, where do you get your information regarding this medication from?

Would it be OK if I read out a case study about a resident in a residential care facility with challenging behaviour, and ask some questions?

*A resident at your care home, Mrs Moss, is 83 and has been living at the RCF for just over a year. Mrs Moss has advanced Alzheimer's disease, in addition to mild elevated blood pressure, high cholesterol and incontinence. Her behaviour has worsened of late and she has started calling out for the nursing staff continuously. She seems to be most vocal in the middle of the night and the other residents have complained about not being able to sleep when she calls out.*



29. How would you respond in this case?

30. Do you feel that medication should be prescribed to reduce Mrs Moss's calling out?

*A small dose of risperidone was ordered for Mrs Moss. After three months, you are performing a routine care plan for Mrs Moss. You have noticed that she rarely calls out for staff. The other nursing staff members also say that her behaviour has been stable over the past few months.*

31. With this in mind what further action would you take with regard to medication management?

32. Are there any ways, in your opinion, to improve the management of challenging behaviour in residential care?

*I just want to thank you very much for helping me with my research project. Those were all the questions I wanted to ask you. Is there anything you would like to add, or anything you feel is important that we have left out? Would you like to clarify any comments you have made?*

***“The quality use of medicines to manage behavioural and psychological symptoms in residential care”.***

(N.B The schedule that follows is for a semi-structured interview, thus, the ordering of the questions will vary according to the way the interview evolves. Other questions not listed in this schedule may be asked to expand a topic if/as it emerges in the interview)

**Pharmacist Interview Schedule/ Topic outline**

*For this study, I would like to examine some of the issues surrounding the management of challenging behaviour in residential care facilities. I am hoping to hear the experiences and opinions of pharmacists around some of the issues found in this patient group.*

*To start with, do you mind if I ask you a few questions about providing pharmaceutical care services to residential care homes?*

33. May I ask how long you have been providing services for the ..... Residential care facility?
34. What services do you provide for the residential care facility? Are you accredited to do RMMRs?
35. Do you visit other homes? How many homes would you service all together?
36. You may be aware that a Medical Journal of Australia series on General Practice and Aged care this year reported an increase in the provision of services to patients in residential care facilities. Do you feel that your pharmacy is asked to provide more services to residential care facilities than, say five years ago?
37. Do you think there are any barriers to providing pharmaceutical care services to residential care facilities?
38. What do you think can be done to address these problems?
39. Can you recall a recent query that you have had regarding a patient in a RCF concerning the management of challenging behaviour? Could you provide further details?
40. Can you recall an instance where the relatives of residents in a residential care facility have sought your advice on the management of their relative's behaviour? Could you tell me what happened?
41. How well equipped do you feel to answer queries from residential care staff or GPs about psychotropic medications prescribed for this indication?
42. Have you attended any training courses on the use of agents like antipsychotics or other medications used in the management of challenging behaviours ?

43. Are there any guidelines that you refer to on the management of challenging behaviours?
44. What is your opinion on the appropriateness of the use of antipsychotics for challenging behaviours in residential care facilities?
45. Have you encountered any side effects associated with the use of antipsychotics for this indication? If so, could you describe these?
46. What do you feel is an appropriate duration for the use of antipsychotics?
47. There have been some problems documented regarding the use of benzodiazepines in the older population. What are your thoughts about the use of benzodiazepines in the RCFs that you service?
48. What do you think is an appropriate duration for residents to be taking benzodiazepines?  
  
If a new psychotropic medication had been prescribed, would you assess if it was effective or not? How would you do this?
- 49.
50. When performing medication reviews what recommendations do you make regarding psychotropic drugs in residents?
51. Do you think that GPs know about the adverse reactions associated with the use of psychotropics?
52. Have you ever been asked to reduce a resident's benzodiazepine usage?
53. have you ever recommended that doses of benzodiazepines are reduced? What was the response to your recommendation?
54. When you perform medication reviews, what percentage of your recommendations would be acted upon by the GPs? How do you feel about this?
55. Do you involve the nursing staff at the RCF when you perform your medication reviews? In what ways do you involve them?
56. Do you think that GPs know about the ADRs associated with the use of psychotropics?
57. Do you think that the medication review service is well accepted by the GPs and nursing staff? Why/why not?
58. if applicable...You stated previously that your pharmacy provides training for the nursing staff at the facility. Can you give me an example of the training you have provided?
59. How well received is the training you provide?
60. May I ask if you or your pharmacy has performed a Drug Usage Evaluation (DUE) ,also known as a clinical audit, for the residential care facility?

61. How would you feel about performing a DUE on the use of psychotropic drugs, say on benzodiazepines for instance?

Would it be OK if I read out a case study, about a resident in a residential care facility with challenging behaviour, and ask some questions?

*“One of the residents, Mrs Moss, is 83 and has been living in the residential care facility for just over a year. Mrs Moss has advanced Alzheimer’s disease, in addition to mild hypertension, hyperlipidaemia and incontinence. One of the nursing staff approaches you whilst you are at the home to ask about Mrs Moss. Mrs Moss has recently started to call out for the nursing staff continually. She seems to be most vocal in the middle of the night and other residents have complained about not being able to sleep when she calls out.”*

62. How would you respond in this case?

*The DON is quite keen for you to recommend something she can suggest to the GP to prescribe for Mrs Moss to control this calling out.*

63. How do you feel about this?

*Mrs Moss is eventually prescribed a small dose of risperidone. After three months, you are in the RCF and see the nurse who asked you about Mrs Moss. You ask about her ‘calling out’ problem and are told that this behaviour has improved markedly over the last months.*

35. With this in mind what further action would you take with regard to medication management?

64. Are there any ways, in your opinion, that pharmacists could assist in the management of challenging behaviour in residents?

*I just want to thank you very much for helping me with my research project. Those were all the questions I wanted to ask you. Is there anything you would like to add, or anything you feel is important that we have left out? Would you like to clarify any comments you have made?*

***“The quality use of medicines to manage behavioural and psychological symptoms in residential care”.***

(N.B The schedule that follows is for a semi-structured interview, thus, the ordering of the questions will vary according to the way the interview evolves. Other questions not listed in this schedule may be asked to expand a topic if/as it emerges in the interview)

**GP Interview Schedule / outline**

*For this study, I would like to examine some of the issues surrounding the management of challenging behaviour in residential care facilities. I am hoping to hear the experiences and opinions of GPs around some of the issues found in this patient group.*

*To start with, do you mind if I ask you a few questions about consulting at residential care homes?*

65. May I ask how long you have been seeing patients at the ..... residential care facility?
66. How many patients would you visit there on a regular basis?
67. Do you have a regular scheduled time to visit the facility? Can I ask what time this is?
68. Are you often called out after hours to see residents? For what sort of reasons?
69. Do you feel that you are ever called into the nursing home unnecessarily? Could you give an example?
70. Do you visit patients at other homes? How many homes would you attend all together?
71. You may be aware that a Medical Journal of Australia series on General Practice and Aged care this year reported an increase in the provision of services to patients in residential care facilities. What are your thoughts on this finding?
72. Would you tell me about any potential barriers you experience in regards to attending Residential Care Facilities – say for example, access to tests/staff/ time constraints?
73. What do you feel can be done to address these issues?
74. Moving on to the management of behavioural and psychological symptoms. The MJA has said that many RCF consultations involve mental health issues, especially those related to dementia. How frequently are you called upon to manage residents with these symptoms in the residential care home setting?

75. For the next few questions, I would like to ask you to recall a recent case of a patient with a challenging behavioural symptom in the residential care facility ? Could you describe the behaviour for me?
76. Do you know if any prior attempts had been made at the home to manage the behaviour before you were contacted? What methods/procedures were used? Do you agree that this was the most appropriate course of action?
77. Can I ask how you dealt with the problem behaviour?
78. Who contacted you about the problem with behaviour? Is this how you are ordinarily contacted about a problem with behaviour in a patient ?
79. Can you recall an instance where the relatives of residents have sought your advice on the management of their relative's behaviour or have asked you to visit their relative in a residential care facility due to a problem with behaviour?
80. Do you ever feel that you are expected to prescribe a medication when contacted about the management of a challenging behaviour in a resident? How do you deal with this expectation?
81. What do you feel about the non-pharmacological treatment of behavioural and psychological symptoms of dementia? Distraction techniques or environmental modifications for instance?
82. Are there any guidelines that you refer to before prescribing medications for this indication? What are they?
83. Are there are certain medications that you feel work well in such residents? Could you outline these?
84. Do you have any concerns about prescribing these types of medications? If so, what are they?
85. Have you encountered any side effects associated with the use of antipsychotics for challenging behaviour? If so, could you describe these?
86. There have been some problems documented regarding the use of benzodiazepines in the older population. What are your thoughts on the use of benzodiazepines in this patient group?
87. Have you had much experience with reducing benzodiazepine dosage or withdrawal programs? Do you think they would be successful in this setting?
88. Would you ordinarily check if a resident's behaviour had improved or stabilised after medication had been prescribed?
89. How often are you called into the residential home to review the use of medications used to manage behavioural symptoms such as antipsychotics or benzodiazepines?
90. Would the resident's family be contacted before/when these medications are prescribed?

91. How involved do you feel most of the relatives want to be in these sorts of cases?
92. How involved do you think they should be?
93. Do you ever participate in multi-disciplinary case conferences in residential homes about the management of patients? How often would these occur? Do you find them worthwhile/beneficial?
94. Medication reviews are routinely performed by pharmacists in this facility? What do you think are the benefits and disadvantages of this service?
95. Do the accredited pharmacists often provide advice to you on reviewing psychotropic medication?

Would it be OK if I read out a case study, about a resident in a residential care facility with challenging behaviour, and ask some questions?

*“A patient of yours, Mrs Moss, is 83 and has been living in the residential care facility for just over a year. Mrs Moss has advanced Alzheimer’s disease, in addition to mild hypertension, hyperlipidaemia and incontinence. The Director of Nursing (DON) approaches you whilst you are at the home to ask about Mrs Moss. Mrs Moss has recently started to call out for the nursing staff continually. She seems to be most vocal in the middle of the night and other residents have complained about not being able to sleep when she calls out.”*

96. How would you respond in this case?

*The DON is quite keen for you to prescribe something for Mrs Moss to control this calling out.*

97. How do you feel about this?

*Mrs Moss is eventually prescribed a small dose of risperidone. After three months, you are called into the RCF to review Mrs Moss’s cholesterol level. You ask about her ‘calling out’ problem and are told that this behaviour has improved markedly over the last months.*

35. With this in mind what further action would you take with regard to medication management?
98. Are there any ways, in your opinion, to improve the management of challenging behaviour in residents?

*I just want to thank you very much for helping me with my research project. Those were all the questions I wanted to ask you. Is there anything you would like to add, or anything you feel is important that we have left out? Would you like to clarify any comments you have made?*

***“The quality use of medicines to manage behavioural and psychological symptoms in residential care”.***

(N.B The schedule that follows is for a semi-structured interview, thus, the ordering of the questions will vary according to the way the interview evolves. Other questions not listed in this schedule may be asked to expand a topic if/as it emerges in the interview)

**Family representative Interview Schedule**

*For this research, I would like to look at how residents in residential care facilities with behaviour that can be difficult are managed. I am hoping to hear your experiences and opinions regarding your relative and how you feel about the management of these sorts of behaviours.*

1. To start with, could you tell me about your relative and how she or he came to be in the residential care facility?
2. How long has she/he been at the RCF?
3. Does your relative still have the GP he used to have before he moved into the Residential Care Facility? If no, did you nominate another GP?
4. Can I ask what health problems does your relative have at this time?
5. We know that many people in residential care will show changes in their behaviour. For example, they may wander off or become upset over very minor things. Did you find that your relative has any of these signs? Could you tell me about any changes to his/her behaviour?
6. Have these behaviours changed at all since they moved in the residential care home?
7. Have you been consulted about any problems with behaviour concerning your relative at the residential care facility by the nursing staff at the RCF?
8. Have you ever participated in a meeting with nursing staff and the GP at the residential care facility about the care and management of your relative?
9. Do you know what medications your relative is currently taking? If yes, could you tell me the names of the ones you remember?
10. Do you know if your relative is taking any tablets to help manage behaviour
11. Does the staff at the residential care facility keep you informed about the medications your relative is taking? Do you want to know this information?
12. What sort of information do you think is important to know about medicines your relative is taking?



13. Does the GP or nursing staff discuss the possible side effects of a medication that your relative has been prescribed? If no, would you like to know this information?
14. Can you recall a time when you discussed a problem about your relative's medicines with the GP or the nursing staff?
15. Do you ever worry about the medicines that your relative takes?
16. What sort of concerns do you have about them?
17. Whom would you tell about these concerns?
18. Would you ever go to a pharmacist and discuss the medicines your relative is taking? Where would you find information about these medicines?
19. Does your relative have problems with sleeping? If so, are they prescribed anything to help them get to sleep or stay asleep?
20. Could I go through a little case scenario with you? Please be assured, this is not happening with your relative. It is just theoretical. If, just as an example, your relative started calling out continually for the nursing staff and some of the other residents were complaining, would you want to know about this?
21. What sort of things would you want to know?
22. If the nursing staff or GP said that they wanted your relative to start some new tablets that might control this behaviour, how would you feel about this?
23. Would you like to know any other information? If so, what information would you like to know?
24. If you found out that these tablets caused side effects, how would you feel about your relative taking them?

*I just want to thank you very much for helping me with my research project. Those were all the questions I wanted to ask you. Is there anything you would like to add, or anything you feel is important that we have left out? Would you like to clarify any comments you have made?*



*Human Research  
Ethics Committee  
(Tasmania) Network*



## **Social Sciences Full Committee Application (full committee approval)**

**NB:** To review the instructions for each section, simply place the cursor over the yellow comment boxes. The instructions will appear on screen for you to read. **(To turn comments off, select 'View' – 'Markup'.)**

Send signed copy to :	<b>Marilyn Knott, Ethics Officer – Social Sciences</b> Research Services, Private Bag 1, Hobart, Tasmania 7001 Australia <b>To speed up processing, the form and attachments can be emailed to</b> <a href="mailto:Marilyn.Knott@utas.edu.au">Marilyn.Knott@utas.edu.au</a> - followed by hard (signed) copy in the mail.
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### **1. TITLE OF INVESTIGATION**

*" The quality use of medicines to manage behavioural and psychological symptoms in residential care. "*

### **2. APPLICANTS** (Note separate section below for student investigators.)

Title/Name	Position	School or Discipline
Chief Investigator/Supervisor Professor Gregory Peterson	Professor Pharmacy Practice	School of Pharmacy
'Phone	6226 2197	Email address   g.peterson@utas.edu.au

Other Investigator Professor Andrew Robinson	Professor Aged Care research	School of Nursing and Midwifery
'Phone	6226 4735	Email address   Andrew.Robinson@utas.edu.au

## **STUDENT INVESTIGATOR - ALL DETAILS MUST BE COMPLETED**

Student Name	Student ID No.	Date of birth	Honours, PhD etc.
Juanita Louise Westbury	082852	24Mar64	PhD
Student email address: <a href="mailto:Juanita.Westbury@utas.edu.au">Juanita.Westbury@utas.edu.au</a>		Phone: 6226 1966	Mobile: 04055 17402

#### 4. OUTLINE OF PROPOSAL

##### Aims

The research project outlined is the second phase of a PhD degree investigating the management of psychological and behavioural symptoms exhibited by residents in Residential Care Facilities. (RCFs)

This project aims to achieve understanding of the way psychological and behavioural symptoms are currently managed in Residential Care.

Through the use of semi-structured interviews with RCF staff, visiting health professionals, and 'enduring guardian' or 'person responsible' representatives of residents, it is aimed to establish:

- What assessment process is involved when a resident displays challenging behaviour and/or psychological symptoms?
- Whether non-pharmacological techniques are routinely employed to manage psychological and behavioural, symptoms, and, if so, what techniques are trialed.
- If medications are prescribed, are they selected and utilised according to good practice guidance?
- What are the roles of nursing staff, GPs and pharmacists in the use of medications for this indication?
- The extent of 'enduring guardian' or 'person responsible' involvement in the management of those residents with challenging behaviour.

##### Justification

Many residents in RCFs will display psychological and behavioural symptoms such as wandering, apathy, agitation, sleep disturbance, anxiety, depression and delusions, with Australian studies reporting an overall prevalence ranging from 29-92%.(1) It is estimated that up to 90% of people with dementia develop these symptoms which are a leading cause of stress for the resident, carers and nursing staff, and are often the reason for admission into RCFs.(1,2)

Studies have shown that psychological and behavioural symptoms are common in RCFs.(3) The first step in effective management of these behaviours is to exclude and reduce possible contributing factors such as medical or other triggers.(4) For example, infections can often exacerbate confusion and many drugs taken by older residents can also contribute to worsening of behaviour.

If these symptoms become problematic, non-pharmacological approaches to manage behavioural and psychological symptoms, are recommended.(4) Medication should be regarded as second-line, due to lack of efficacy and potential for side effects.(5) However, previous research has revealed that psychotropic drugs, mainly antipsychotics and benzodiazepines, are over-prescribed in Residential Care Facilities.(6) When these medications are prescribed, the lowest effective dose should be administered and dose reductions trialled on a regular basis.(4) Concern has been raised in Australia, and internationally, about the inappropriate use and review of these drugs in residents.(1,7)

Although several researchers have linked psychotropic usage in RCFs to variables such as the demographics of residents, facility characteristics and degree of behaviours of concern, there are few studies to date that have examined the variables within the care home environment that may influence psychotropic prescribing.(8,9) Such factors could include what assessment process is involved before medication is prescribed, if non-pharmacological methods are trialled before medication is initiated, how often GPs review residents and their medication, the involvement of the resident's family in prescribing decisions, and the underlying attitudes of staff towards challenging behavioural and psychological symptoms.

This project is the first known study to adopt a qualitative approach to examine, in depth, why and how these medications are chosen and utilised for the treatment of behavioural and psychological symptoms in residential care. The study will increase our overall understanding of the factors that influence the prescribing and appropriate use of psychotropic medications in the residential care environment.

At a later stage, the information from this study will be used to tailor interventions for assessment within a randomised controlled trial design, to ensure the quality use of psychotropic medicines to treat behavioural and psychiatric symptoms of those persons residing in RCFs.

##### Period of investigation

Commencement date: 2 January 2007

Completion date: 31 March 2008

<b>5. FUNDING</b>		
Do the investigators have any financial interest in this project?	Yes	No X
<b>If this Application relates to a Grant or Consultancy, please indicate the title and Number relating to it:</b>		
Funding Bodies:	Amounts	
<b>6. REVIEW OF ETHICAL CONSIDERATIONS</b>		
Has this protocol <b>previously</b> been submitted to a committee operating within the HREC (Tasmania) Network If 'yes' please indicate when and the reference	Yes	No X
Does this project need the approval of any other Ethics Committee?	Yes	No X
Do the investigators have any personal or professional association with the intended research cohort?	Yes	No X
<b>If YES</b> please indicate the nature of this association.		

<b>7. APPROVALS FROM OTHER DEPARTMENTS/INSTITUTIONS</b> (i.e. Department of Education, Particular wards in hospitals, Prisons, Government Institutions, Businesses)		
Does this project need the approval of any other Institution?	Yes	No X

<p><b>8. RELEVANT LITERATURE REFERENCES</b></p> <ol style="list-style-type: none"> <li>Woodward MC. Pharmacological treatment of challenging neuropsychiatric symptoms of dementia. J Pharm Pract Res 2005;35:228-34.</li> <li>Brodaty H, Draper B, Low L. Behavioural and psychological symptoms of dementia: a seven-tiered model of service delivery. MJA. 2003;178:231-34.</li> <li>Medical care of older persons in residential aged care facilities. RACGP – 'Silver Book' National taskforce. Nov 2005. ;4th Ed.</li> <li>IPA. BPSD: Introduction to Behavioral and psychological symptoms of dementia. ©International Psychogeriatric Association. 2002 [cited Nov 2006]; Available from: <a href="http://www.ipa-online.org">http://www.ipa-online.org</a></li> <li>Cohen-Mansfield J. Non-pharmacologic interventions for inappropriate behaviours in dementia. Am J Geriatr Psychiatry. 2001;9:361-81.</li> <li>NICE. Practice guide NICE/SCIE: Dementia: supporting people with dementia and their carers in health and social care (NICE clinical guide 42) November 2006.</li> <li>Ballard C, Waite J, Birks J. Atypical antipsychotics for aggression and psychosis in Alzheimer's disease. Cochrane Database of Systematic Reviews 2006, Issue 1. Art No.:CD003476.</li> <li>Kim H, Whall A. Factors associated with psychotropic drug usage among nursing home residents with dementia. 2006 Nurs Res; 55(4) 252-258.</li> <li>Briesacher B, Limcangco R, Simoni-Wastila L, al e. The quality of antipsychotic drug prescribing in nursing homes. Arch Intern Med. 2005;165:1280-85.</li> <li>Pope C, Zieblands S, Mays N. Analysing Qualitative data. BMJ 2000;320:114-116.</li> </ol>
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## 9. PROCEDURES

### Detailed procedures

This research project is part of a PhD project and involves a qualitative study which aims to examine the attitudes, beliefs and behaviours of the staff, health professionals and families of residents around the management of behavioural and psychological symptoms in residential care. Through the use of semi-structured interviews with 10 nursing staff (5 registered nurses and 5 enrolled nurses), 5 General Practitioners, 5 Pharmacists working in the RCF setting and 10 'enduring guardian' or 'person responsible' representatives of residents, it is intended to record examples, narratives and explanations to increase our understanding of how challenging behaviours are managed in residential care and establish why and how medicines are chosen and utilised for the treatment of psychological and behavioural symptoms.

A preliminary study was completed recently by the research team in which the prescribing rates of psychotropic medication in 2006 were calculated for 40 Tasmanian RCFs. This study received ethical approval in March 2007. ( Ethics reference: H9299) Five RCFs from this sample, all located in Hobart, will be purposely selected and invited to participate as sample sites. It is aimed to select five medium to large sized facilities with high psychotropic prescribing rates. The rationale underlying the selection of this sample is to seek the opinions, experiences and attitudes of staff, GPs, pharmacists and 'enduring guardians' or 'persons responsible' in homes that are known to utilise a higher than average amount of psychotropic medication. As one of the aims of the study was to identify factors that influence psychotropic prescribing, it was felt that this sample of high psychotropic prescribing facilities was the most appropriate to obtain this qualitative data..

### Interviews

Each of the selected residential care facilities will be contacted regarding the study via a letter outlining the study, sent an information sheet and invited to participate. Once a RCF has agreed to become involved, the Director of Nursing at the home will be contacted and asked to provide the names of the service pharmacy and several GPs that regularly visit the facility. These named pharmacy proprietors and GPs will be sent a letter and study information sheet in which they will be invited to participate. They will be phoned at a later date by the researcher who will ask if they are interested in participating. To recruit nursing staff participants, a researcher will address a staff meeting at each RCF about the study, provide information sheets and ask for both a registered and enrolled nurse representative. The letters and information sheets are attached to this application.

All 'enduring guardians' / 'person responsible' of residents with psychological/ behavioural symptoms will be invited to attend via third party recruitment. The Director of Nursing will contact the "enduring guardian" or 'person responsible' of several residents exhibiting challenging behaviour and forward them a letter and an information sheet about the study. If these representatives are interested in participation, or require more information about the research they will contact the research team directly. Contact details of the university researchers will be provided for them to do this.

After participant's consent is gained and the consent form completed an interview will be arranged at a time and place convenient for the participant. The interview schedules of the nursing staff participants are planned to include questions to evoke their experiences of dealing with the challenging behaviours of residents Views will also be sought relating techniques employed to manage behavioural and psychological symptoms including the use of drug therapy. The GP and pharmacist interview schedules will be similar but vary according to profession. For example, the GPs will be asked about why they prescribe psychotropic medication and involvement with the nursing home. The pharmacists will be asked about their experience with psychotropic use and review of these medications in the residential care home environment. The 'enduring guardian' or 'person responsible' will be asked about their involvement in the management of challenging behaviour for their relative and desired input when prescribing decisions are made. The interview schedules of all participant groups are attached.

All participants will be asked if they will allow their interview to be recorded digitally. The recorded interviews will be transcribed in full and analysis based on the typed manuscripts.

### Data Analysis

The methodology utilised to analyse the transcripts will be content analysis which follows the principles of 'grounded theory' whereby concepts, categories and themes are identified and developed as they emerge from the interview.(10). NVivo 7 qualitative software package will be utilised to assist in the interpretation of the data.

### Where is this project to be conducted?

Hobart. Interviews will be conducted at the residential care facilities, community pharmacies, GP practice surgery, in people's homes or in a place that the participant elects.

## **10. SUBJECTS**

### **10.1 Selection of subjects**

As outlined above, five RCFs will be purposely selected and invited to participate in this research project. Five medium to large sized facilities with high psychotropic prescribing rates will be initially invited. This sample was selected with the aim of examining the reasons underlying the selection of pharmacological management of behavioural and psychological symptoms, and to compare practices, attitudes and beliefs at the high psychotropic use facilities with that of the low psychotropic rate facility.

Semi-structured interviews will be conducted with two nursing staff, two 'enduring guardians' or 'persons responsible' representatives of residents with challenging behaviour, and a GP and pharmacist associated with each residential facility. It is thought that this sample will provide a wide range of opinions and experiences of those groups associated with the management of challenging behaviours in RCFs.

Only the 'enduring guardian' or designated 'person responsible' for a resident will be invited to participate in this study. The Guardianship and Administration Act (1995) states that only these persons are legally appointed to make medical and lifestyle decisions on behalf of the resident. The research team has a copy of this Act and associated documentation and is fully aware of other potential advocates who may be authorised to speak for a person with dementia (e.g. those with power of attorney – this advocate does not have the authorisation to make medical decisions for the resident who is unable to make informed decisions for themselves)

The research team is also aware that in the case that a resident is unable to give consent for medical treatment, substitute consent is legally required from the 'enduring guardian' or 'person responsible'. There may be times in the interviews where breaches of the guardianship act are suspected. For instance, the enduring guardian may say that they were not involved when a prescribing decision was made.

We have contacted the legal officer at the Guardianship Board to discuss the implications of uncovering suspected breaches of the Guardianship Act. The advice we have received is that due to the design and scope of this study, the researchers will not have any access to medication or medical records. This means that the researcher cannot verify if consent has been obtained and formally documented, or, indeed if suspected alterations have been made to the resident's medications. An actual breach of the Act is unable to be verified and would be classified as a 'suspected' breach or an 'allegation'.

Before the interview is started, the researchers will supply the 'enduring guardian' or 'person responsible' with a fact sheet regarding their rights to give consent for treatment from the Guardianship board. This is attached to this application. Interviews will only be conducted after the legal status of 'enduring guardian' or 'person responsible' is confirmed by the participant.

If a 'suspected' breach is uncovered during the interview, the interviewer will refer the participant to the guardianship fact sheet. It will be the participant's responsibility to follow up any concerns they may have regarding consent.

### **10.2 Recruitment of subjects**

The interview participants will be associated with each of the residential homes selected for the study. Each group will be recruited separately as follows:

#### Nursing staff

With the consent of the Director of Nursing at each RCF, a researcher will attend a staff meeting to outline the study and provide information sheets about the research. Registered and enrolled nurses will be invited to participate. After consent is obtained, an interview will be held with the first nursing representative in each group to volunteer.

#### GP and Pharmacist

The Director of Nursing at each facility will be asked to provide the names of the supply pharmacy and the names of several GPs that visit the facility to the research team. The service Pharmacy and individual GPs will be sent a letter and information sheet about the study and invited to participate in an interview. All service pharmacies and GPs will be phoned to ascertain if they give consent to be interviewed. The Pharmacy will be asked to nominate a pharmacist to participate in the research and the first GP to volunteer to participate from each facility will be interviewed.

#### Enduring guardian/Person responsible with psychological and/or behavioural symptoms

Recruitment of this participant group will be via third party. The Director of Nursing at each facility will be asked to contact four or five 'enduring guardians'/'people responsible' of residents with behavioural and psychological symptoms and briefly discuss the study. If receptive, the 'enduring guardian' or 'person responsible' will be given a letter and study information sheet about the project. After reading the information sheet, if the 'enduring guardian' or 'person responsible' wishes to participate they can contact the research team directly or post a signed consent form to the researcher. The first two 'enduring guardian' or 'person responsible' from each home that agrees to participate will be interviewed.

<b>De-Identified</b>	<input type="checkbox"/>
<b>Re-Identifiable</b>	<input checked="" type="checkbox"/>
<b>Identifiable</b>	<input type="checkbox"/>
<p><i>If the information is Re-Identifiable or Identifiable please give details of the information that will be collected. Also indicate how the confidentiality and anonymity of the participants will be protected:</i></p> <p>The information that will be collected in this study will be taped interviews which will be transcribed and anonymised. Identification codes will be assigned to each interview and recorded on the consent forms. The consent forms will be held in a secure manner in a locked filing cabinet at the School of Pharmacy.</p> <p>All personal information will be removed from the interviews in the course of the transcription so that it will not be possible to identify individuals from any written documents, reports or publications produced during the research. All tapes will be held in a secure manner available only to the researchers. Upon analysis of the data, the tapes will be destroyed.</p>	
<p><b>10.4 Will any personal information be collected from sources other than the subjects themselves? :</b> No</p> <p>If <b>YES</b>, please declare the sources of the Information i.e. medical records, databases, registries, lists of members from Associations, clubs etc:</p>	
<p><b>10.5 Will data on individual subjects be obtained from any Commonwealth Government agency without seeking the Consent of the Individuals?</b> No</p>	
<p><b>10.6</b> Will the project target Aboriginal and/or Torres Strait Islander peoples: No</p>	
<p><b>10.7</b> Will the project impact on and use other collectivities? If yes, please indicate the association, cultural group, ethnics groups you will use for reference No</p>	

## 11. POTENTIAL RISKS

### 11.1. Identification of the Risks:

#### 1. Obtaining data containing personal information

The data collected throughout this study will be obtained through the use of semi-structured interviews with participants. It will be necessary to know the participants names and participant group for the purpose of organising the interview and asking pertinent questions.

#### 2. Potential for emotional distress, anxiety or embarrassment

All qualitative research, in particular to do with health or social issues, has the potential to cause emotional distress, anxiety or embarrassment. This study involves a semi-structured interview about the management of residents in aged care. Some people may experience discomfort or distress when talking about caring for a loved one or matters to do with the health of a relative. It is also appreciated that some staff and health professionals may experience stress or personal conflict issues relating to the practice of prescribing psychotropic medication for the management of psychological and behavioural symptoms. However, evidence shows that the majority of people enjoy participating in interview-based research. The interviewer is trained to address any emotional issues which may arise during the interview. In addition, there will be opportunities to debrief. If a particular question or line of questioning is shown to cause undue distress, it will not be pursued in the current interview and its use will be reviewed for subsequent interviews. In addition, the participant will also be advised that they can stop the interview at any time if they feel stressed. In the unlikely event that a participant becomes stressed, an experienced counsellor is available to consult with the participant. We would like to

emphasise that research members have had extensive experience conducting this type of research over many years with little difficulty.

## **11.2. Precautions taken to mitigate the risks**

### **1. Obtaining data containing personal information**

All participants will be assigned with an identifier code which will be used for the collection and storage of data. The transcript of each interview will be de-identified with any identifying data such as names removed during transcription. Participant names and contact details will not be recorded and participants will be identified by code in the collection, storage, transcription and analysis of data. The identification codes will be recorded on consent forms which will be kept in a locked filing cabinet at the School of Pharmacy.

### **2. Potential for emotional distress, anxiety or embarrassment**

The interviewer is trained to address any emotional issues which may arise during the interview. In addition, there will be opportunities to de-brief after the session and the information sheet contains details of the appropriate avenues if they wish to take the matter further. The consent form states that participants are entitled to withdraw at any time without providing a reason and without negative repercussions.

If a particular question or line of questioning is shown to cause undue distress, it will not be pursued in the current or subsequent interviews. In the unlikely event that a participant becomes stressed, an experienced counsellor is available to consult with the participant. It should be noted that research members have had extensive experience conducting this type of research over many years with no known incidences of this nature.

## **12. REMUNERATION**

**Dependent on the outcome of a funding application to the School of Pharmacy:**

All participants of the study will be offered remuneration to the extent of \$100 per participant. This gratis payment will be made upon completion of the interview.

## **14. CONFIDENTIALITY**

The identity of all interview participants will be kept confidential and tape transcripts processed and stored in a de-identified manner. All transcripts will be kept at the University of Tasmania premises for a period of five years minimum. Storage will be secure, in locked filing cabinets, or password protected computers. Only the researcher conducting the interviews and chief investigators will have access to information gathered.

**All raw data must be held by the responsible institution (ie UTas, DHHS, AMC) for a period of at least 5 years from the date of publication (This includes the publication of the thesis). The data may be kept for longer than 5 years.**

Where will the data be kept (e.g. which School) **School of Pharmacy**

How will the data will be kept secure (in locked cabinets or secure servers):  
**Locked cabinets and password protected computers**

How will the data be destroyed? **All interview transcripts will be shredded.**

**Are AudioTapes and Videotapes being used to record data?** Yes

If **YES** then please indicate how the anonymity of the participants is going to be protected:

Tapes will be identified using an identifier code and will be transcribed without any identifying information being recorded (such as names, race, address, work details). All tapes will be stored in locked cabinets and then destroyed upon transcription. All tape transcripts will be stored in a locked filing cabinet and on computers in a secure manner in computers with password access to researchers only.



## 15. ANONYMITY

**If an assurance of anonymity in the research output has been given to the participants, how will this anonymity be assured?**

Each of the interview participants will be assigned an identifier code which will be utilised for the collection and storage of data. This identifier code will be assigned and recorded on the consent sheet. These consent sheets will be kept in a locked filing cabinet at the School of Pharmacy. Participants names, addresses and phone numbers will not be recorded. Interview information will be de-identified throughout the transcription process. Participants will be identified by code in collection, storage, transcription and analysis of data.

**15.2 Are Focus Groups involved in this project?**

No

## 16 ADMINISTRATION OF SUBSTANCES OR AGENTS not applicable

## 17. OTHER ETHICAL ISSUES not applicable

## 18. INFORMATION SHEET

**Is the Information Attached?**

Yes

## 19. CONSENT FORM

**Is the Consent Form Attached?**

Yes

## 20. DECLARATIONS

### Statement of scientific merit

The **Head of School\*** is required to sign the following statement:

- This proposal has been considered and is sound with regard to its merit and methodology.
- The Head of School's (or Head of Discipline's) signature on the application form indicates that he/she has read the application and confirms that it is sound with regard to:
  - (i) educational and/or scientific merit and
  - (ii) research design and methodology.

If the Head of School/Discipline is one of the investigators **this statement must be signed by an appropriate person**. This will normally be the Head of School/Discipline in a related area or by the Dean.

This does not preclude the Committee from questioning the research merit or methodology of any proposed project where it feels it has the expertise to do so.

Professor Stephen Aldous

(Name of Head of School)

(Signature)

(Date)

\* In some schools the signature of the Head of Discipline may be more appropriate.

\* The certification of scientific merit may not be given by an investigator on the project.

### Conformity with NHMRC guidelines

The *chief investigator* is required to sign the following statement:

I have read and understood the *National statement on ethical conduct in research involving humans 1999*. I accept that I, as chief investigator, am responsible for ensuring that the investigation proposed in this form is conducted fully within the conditions laid down in the *National Statement* and any other conditions specified by the University Human Research Ethics Committee.

Professor Gregory Peterson

(Name of chief investigator)

(Signature)

(Date)

## RedUSE Psychotropic clinical audit program, data entry page

**Generate a DUE from the drugs entered into the Webster program.**

### RedUSE Data Entry

**Select Study Period** ☒ week 0 ☐ week 12 ☐ week 26

**Select Nursing Home** My Nursing Home 1 **Date** 3/07/2008

**Only Show patients who are :** ☒ Active ☐ Inactive ☐ All

**Patient's Regular Drugs**

Drug Name	Dose Per Day	Instructions
Abilify 30mg Tab	1	
Alendro Once Weekly 70mg Tab	0.1429	
Dapa-Tabs 2.5mg Tab	1	
DBL Aspirin 100mg Tab	1	
natures way	1	
Nexium 40mg Tab	2	
Noten 50mg Tab	0.5	
Stildem 10mg Tablet	1	

**Add Regular Drug** Are the regular Meds correct ? ☒ Yes ☐ No

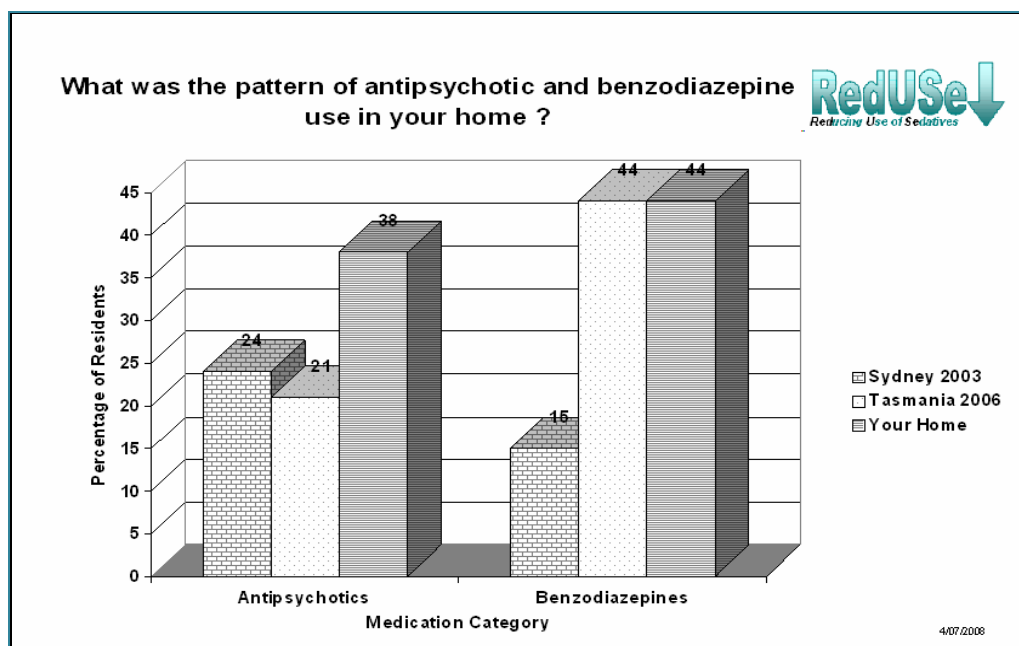
**Patient's antipsychotic, anxiolytic, hypnotic and antidepressant PRN drugs**

Drug Name	Dose per day	PRN medicine is used
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**Add PRN Drug** Are the PRN Meds correct ? ☒ Yes ☐ No

**Print Resident List** **Print Sedative Review Plan** **Generate DUE** **Export Data** **Quit**

## RedUSE report page examples: Provided to each participant aged care home



### Drug Use Evaluation (DUE) – ‘RedUSE’

What is a DUE?

- A Drug Usage Evaluation (DUE) is a cyclic medication audit that promotes ‘continuous improvement’
- A DUE involves:
  - ☐ monitoring medication use
  - ☐ comparing practice, and
  - ☐ modifying practice
- This information for the RedUSE DUE has been collected from your supply pharmacy’s computer records.
- There are 2 DUE cycles in the RedUSE project. This is the first DUE report. The second DUE cycle will commence in Sept 2008.

*The information collected from this DUE will be used:*

1. *To provide a measure of each Residential Care Facility’s (RCF’s) psychotropic medication use with a focus on medications used for their sedative properties.*
2. *For benchmarking with Tasmanian RCF rates from 2006 and Central Sydney rates from 2003...and for comparison with data at 12 and 26 weeks.*
3. *To create a customised training session for nursing staff.*

**NB:** For the RedUSE DUE, the antipsychotics monitored were newer agents like risperidone and olanzapine, and the older agents such as haloperidol. The hypnotics/anxiolytics monitored were mostly benzodiazepines, such as temazepam, oxazepam and diazepam. The antidepressants monitored were the newer agents such as citalopram, sertraline and mirtazapine, and the older tricyclic antidepressants (e.g. amitriptyline, doxepin).

The RedUSE program is funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia. If you would like more information about the RedUSE project please phone Juanita Westbury on 6226 1966 or email [Juanita.Westbury@utas.edu.au](mailto:Juanita.Westbury@utas.edu.au)

## Benzodiazepines

### What are benzodiazepines used for?

- Short-term (2-4 weeks) to manage anxiety and insomnia
- Long-term use (regular use for 4 weeks or more) is not recommended because of the potential for side effects, tolerance and dependency.<sup>1</sup>

### How long does it take to develop tolerance to benzodiazepines?

- Tolerance to the hypnotic effects develops within a few weeks
- Tolerance to the anxiolytic effects develops over a few months.<sup>1</sup>

### Why RedUSE benzodiazepines?

- Continuing treatment in older people is associated with:
  - impairment of cognitive function and memory
  - an increased risk of fractured hips

*A cohort study of 125,203 over 65yr-olds found a 24% increased risk of hip fracture in people taking benzodiazepines compared with those not taking benzodiazepines*

- The benefits of stopping long-term benzodiazepines were shown in a Randomised Controlled Trial of 139 over 65yr-olds<sup>1</sup> which reported that stopping treatment:
  - had no long-term adverse effects on insomnia or anxiety symptoms
  - improved memory, reaction times and alertness
  - improved quality of life measures for function and vitality.

### How to avoid withdrawal symptoms<sup>1</sup>

- Most people only experience mild withdrawal symptoms when withdrawal is slow (e.g. anxiety, insomnia, headache, dizziness)<sup>2</sup>
- The key steps for a successful withdrawal are:
  - assess suitability for withdrawal at the present time (e.g. avoid withdrawal if acutely ill)
  - consider whether conversion to diazepam is indicated
  - gradually reduce dose
  - ensure the withdrawal schedule is flexible and tailored to the individual.

### How to RedUSE?

*The suggested rate of withdrawal is to reduce the current daily dose by 10-20% / week<sup>2</sup>*

	Number of tablets to be taken						
	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Week 1	1.5	2	1.5	2	1.5	2	1.5
Week 2	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Week 3	1	1.5	1	1.5	1	1.5	1
Week 4	1	1	1	1	1	1	1
Week 5	0.5	1	0.5	1	0.5	1	0.5
Week 6	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Week 7	0	0.5	0	0.5	0	0.5	0
Week 8	0	0	0	0	0	0	0

### A sample withdrawal schedule<sup>2</sup>

for a resident taking

2 x 10mg temazepam tablets or

2 x 5mg nitrazepam tablets

## Benzodiazepines....continued

### Why convert to diazepam?

- Diazepam has a long half-life which ensures a gradual fall in blood concentrations
- Diazepam is available in low-dosage tablets which allows for small dosage reductions

*Consider whether conversion to diazepam is indicated.<sup>2</sup>*

- Convert all people taking oxazepam, lorazepam or alprazolam
- Convert people having difficulty withdrawing on temazepam or nitrazepam

### Diazepam equivalence table <sup>1</sup>

5mg diazepam	= 0.25mg alprazolam
	= 0.5mg lorazepam
	= 5mg nitrazepam
	= 15mg oxazepam

### How to convert to diazepam?

- For people on higher doses of benzodiazepines, conversion to diazepam is best carried out in stages, one dose at a time, to avoid daytime sedation.<sup>1</sup>

	morning	midday	evening
<b>Week 1</b>	oxazepam 15mg	oxazepam 15mg	oxazepam 15mg
<b>Week 2</b>	oxazepam 15mg	oxazepam 15mg	oxazepam 7.5mg + diazepam 2.5mg
<b>Week 3</b>	oxazepam 7.5mg + diazepam 2.5mg	oxazepam 15mg	oxazepam 7.5mg + diazepam 2.5mg
<b>Week 4</b>	oxazepam 7.5mg + diazepam 2.5mg	oxazepam 15mg	diazepam 5mg
<b>Week 5</b>	diazepam 5mg	oxazepam 15mg	diazepam 5mg
<b>Week 6</b>	diazepam 5mg	oxazepam 7.5mg + diazepam 2.5mg	diazepam 5mg
<b>Week 7</b>	diazepam 5mg	diazepam 5mg	diazepam 5mg
<b>Week 8</b>	Start diazepam taper		

### A suggested conversion schedule<sup>1</sup>

For a resident taking oxazepam 15mg tds  
15mg oxazepam tds

### Supporting the person during and after withdrawal

- Provide encouragement, support and information to patient, relatives and nursing staff
- Manage any withdrawal symptoms by use of non-drug strategies
- Consider slowing or temporarily stopping withdrawal if withdrawal symptoms become troublesome.<sup>1</sup>

## Tricyclic Antidepressants (TCAs)

- Almost 10% of residents of Tasmanian nursing homes are prescribed TCAs, which is more than twice the rate of use reported in Sydney nursing homes.<sup>1</sup>
- On the basis of a more acceptable side effect profile in the elderly, the usual first choice antidepressant would be SSRIs, mirtazapine, MAO-I (moclobemide), or SNRI (venlafaxine).<sup>2</sup>
- TCAs are second-line antidepressant therapy in older people.<sup>2</sup>
- Reserve TCAs for clinical circumstances where there has been excellent previous treatment response, or where alternate treatment is ineffective or poorly tolerated.<sup>3</sup>

### Side-effects of TCAs in older people

- Older people are more likely to have side effects, such as:
  - anticholinergic effects - dry mouth, constipation, urinary retention and confusion
  - postural hypotension
  - cardiac rhythm alteration in those predisposed.<sup>2</sup>

### Alternatives to TCAs for treating non-mental health conditions

- In many cases low dose TCAs are added to a drug regimen for reasons other than antidepressant effect e.g. urinary incontinence, sleep disturbance and neuropathic pain.
- For many residents, alternative treatment can be trialled in place of a TCA<sup>3</sup>

#### Urinary urge incontinence

Oxybutynin, propantheline, tolterodine

#### Sleep disturbance

Sleep hygiene and assessment, Short-term hypnotics

#### Neuropathic pain

Gabapentin, carbamazepine, topical capsaicin

Alternatives to TCAs for treating non-mental health conditions<sup>3</sup>

### How to RedUSe TCAs?

- It is usual to reduce the TCA dose over a few weeks before finally stopping.

### Antipsychotics in dementia

#### Key messages

- Behavioural and environmental interventions should be first-line management of behaviour
- Antipsychotics have limited efficacy (at best, a 20% response) in the treatment of challenging behaviour
- If an antipsychotic is used, then:
  - Start with a low dose and titrate upwards very slowly according to clinical response
  - Review regularly for efficacy and adverse effects
  - Trial dose reduction/cessation every 3 months.<sup>4</sup>

### How to RedUSe antipsychotics?

- The dose should be tapered by 50% every two weeks and stopped after two weeks on the minimum dose.<sup>4</sup>

#### References:

<sup>1</sup> Snowden J et al. Current use of psychotropic medication in Sydney nursing homes. Int Psychogeriatr 2005;17(4):1-10

<sup>2</sup> NSWHealth 2001 Consensus Guidelines for Assessment and Management of Depression in the Elderly.

<sup>3</sup> DVA Veterans' Mates Therapeutic brief 5 – Antidepressants 2006    <sup>4</sup> DVA Veterans' Mates Therapeutic brief 12 – Antipsychotics in dementia 2007

## Appendix O



The PHARMACY GUILD of AUSTRALIA



### Community Pharmacy promoting appropriate sedative use in Aged Care: the RedUSE project

#### Pharmacist Training

Sat 5<sup>th</sup> & Sun 6<sup>th</sup> July 2008, 'Drovers Room', The Old Woolstore Apartment Hotel, 1 Macquarie St, Hobart, Tasmania

#### Programme

Day 1: Saturday 5<sup>th</sup> July 2008 (12.30hrs – 17.00hrs)

Time	Session : Presenter
12.30 - 13.00	Arrival – light lunch
13.00 - 13.10	Welcome Address and RedUSE overview : Professor Gregory Peterson, Professor of Pharmacy, Unit for Medications Outcomes Research and Education (UMORE), School of Pharmacy, University of Tasmania
13.15 - 14.00	Psychogeriatrics: Behavioural and psychological symptoms in older people: Juanita Westbury, RedUSE project manager, PhD candidate, UMORE, School of Pharmacy, University of Tasmania
14.00 – 14.30	Residential care: first line management of challenging behaviour : Liz Musgrove, Director of Nursing, ADARDS Nursing home, Warrane
14.30 – 15.15	Pharmacological management of behavioural and psychological symptoms in residential care - part 1: Dr Jane Tolman, Geriatrician, Royal Hobart Hospital
15.15 – 15.30	Afternoon tea
15.30 - 16.15	Pharmacological management of behavioural and psychological symptoms in residential care - part 2 Dr Jane Tolman, Geriatrician, Royal Hobart Hospital
16.00 – 16.30	Benzodiazepine use in Tasmania: Dr Nicolle Khelifa, Clinical Psychiatrist, Drug and Alcohol services, Newtown, Hobart
16.30 – 17.00	Psychotropic drug use in Tasmania: Juanita Westbury, RedUSE project manager, PhD candidate, UMORE, School of Pharmacy, University of Tasmania




#### Programme

Day 2: Sunday 6<sup>th</sup> July 2008 (09.00hrs – 15.00hrs)

Time	Session : Presenter
09.00 - 09.15	Arrival – tea and coffee
09.15 - 10.00	QUM and Residential Care Facilities- Influencing change: Dr Shane Jackson, Senior Research Fellow, Unit for Medications Outcomes, Research and Education (UMORE) , School of Pharmacy, University of Tasmania
10.00 - 10.30	The RedUSE project - the strategies: Juanita Westbury, Unit for Medications Outcomes, Research and Education (UMORE) , School of Pharmacy, University of Tasmania
10.30 - 10.45	Morning tea
10.45 - 11.15	The RedUSE DUE – how does it work?: Juanita Westbury, Unit for Medications Outcomes, Research and Education (UMORE) , School of Pharmacy, University of Tasmania
11.15 - 11.45	The Staff training package + CD case study: Juanita Westbury, Unit for Medications Outcomes, Research and Education (UMORE) , School of Pharmacy, University of Tasmania
11.45 – 12.15	Sedative review / Case conferencing / GP collaboration: Dr Shane Jackson, Dr Jonathon Isles, Liz Musgrove, Unit for Medications Outcomes, Research and Education (UMORE), School of Pharmacy, University of Tasmania/ GP /ADARDS
12.15 - 13.00	Lunch – hot buffet
13.00 - 15.00	Putting RedUSE into practice: Panel with Juanita, Shane Jackson, Liz Musgrove, Dr Jonathon Isles. UMORE, School of Pharmacy, University of Tasmania



## Nurse training power point



Reducing Use of Sedatives

UTASS  
UNIMORE  
Tasmanian Ageing Research Centre


### Sedatives

In recent years, the term 'sedatives' is often used when referring to sleeping tablets

Sedative: 'A medication that has a soothing, calming or tranquillizing effect'

In the RedUSE project, sedatives are hypnotics/anxiolytics (mostly benzodiazepines) and antipsychotics

### Sedative use in Aged Care - Outline

- What are sedative drugs commonly used for?  
Sedative medications – benefits and risks
- What is the Tasmanian ACH sedative use?  
.....Introducing 
- What is your own home's pattern of use?
- How to 'RedUSE' sedatives

### What are sedatives commonly used for?

Sleep disturbance - 40-60% of residents  
Anxiety and depression - 34% of residents

- Up to 90% of residents with dementia exhibit challenging behaviours such as delusions, aggression, wandering, cursing and calling out


"Currently more than 75% of people living in care homes have some form of dementia or cognitive impairment."

A recent Tasmanian study found residents with physical aggression caused the most distress for nursing staff

### 'Good Practice' to treat sleep disturbance, anxiety and behaviour of concern

NAPS 1998-2000, NAPS 2000

- Rule out other causes
- Use non-drug strategies



Medications are second-line

- Antipsychotics should only be used in situations where behaviour causes significant distress or risk of harm
  - review use at 3 month intervals
- Benzodiazepines:
  - short-term use only (2-4 weeks)
  - long-term use should be reviewed frequently

### Antipsychotics

Used for schizophrenia and to manage challenging behaviour in people with dementia

Older antipsychotics: haloperidol (serenace), chlorpromazine (largactil), trifluoperazine (stelazine), pericyazine (neudactil)

Newer antipsychotics: risperidone (isperidol), olanzapine (Zyprexa), quetiapine (Seroquel)

- Antipsychotics show a small benefit in reducing aggression in dementia - effective in about 20% of residents with aggression
- Limited effect on behaviours such as wandering or calling out



### Risks associated with antipsychotic use in older people with dementia

#### What are the risks?

confusion, movement disorders, metabolic disturbance and falls

**Cerebrovascular risk (2004) UK**  
antipsychotics in dementia patients increases the risk of stroke almost four-fold

**Mortality risk (2005) US**  
increases the risk of death (1.5 fold increase)

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### WORLD NEWS

#### Neuroleptic risk

Midwestern's patients on sedatives die sooner

Researchers at the University of Michigan have found that patients taking neuroleptic drugs, which are used to treat mental illness, die sooner than those who do not. The study, published in the journal *Journal of the American Medical Association*, found that patients taking neuroleptics had a 1.5-fold increase in mortality risk compared to those who did not. The researchers also found that patients taking neuroleptics had a higher risk of falls, confusion, and other side effects. The study was conducted using data from the Michigan Health and Hospital Survey, which is a large, population-based study of health and hospital use in Michigan.



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### Benzodiazepines

Used for sleep disturbance (temazepam, nitrazepam) and anxiety (diazepam, oxazepam, alprazolam, lorazepam)

In the short-term, benzodiazepines improve sleep but lose their hypnotic effect after 14 days

- Benzodiazepines reduce anxiety, however, non-drug treatment and anti-depressants are often more effective

Limited evidence for use to manage challenging behaviour. Benzodiazepines can worsen behavioural symptoms

9

### Risks of benzodiazepines

#### What are the risks?

confusion, cognitive impairment, falls and hip fractures

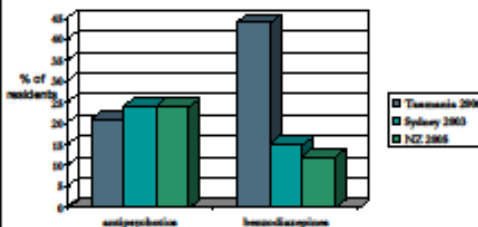


"All benzodiazepine doses greater than 3mg per day in diazepam equivalents increase the risk of hip fracture by 50%."

With prolonged use, dependence and tolerance may occur

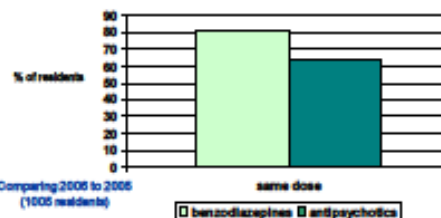
10

### How does Tasmanian ACH sedative use compare with mainland Australia / NZ?



11

### Were antipsychotic and benzodiazepine doses in Tasmanian ACHs regularly altered?



12

### Why are sedatives used in Aged Care homes? – for discussion

- Why do you think the use of benzodiazepines in aged care is higher in Tasmania than in other areas of Australia?
- What is the use of sedative medication in your aged care home?
- Do you think the doses of these medications are often reduced as guidelines recommend?



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### The RedUse↓ Project

**Aim:** To promote the quality use of sedatives

**24 ACHs involved** - 13 in Hobart  
- 11 in Launceston (control)

**Co-ordinated by community pharmacy/pharmacists**

- Involves the use of several strategies – D.U.E, staff training and sedative review/case conferences

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### What is a DUE?

A Drug Usage Evaluation (DUE) is a cyclic medication audit that promotes 'continuous improvement' to achieve quality use of medicines

- A DUE involves:
  - monitoring medication use
  - comparing practice, and
  - modifying practice

**2 DUE cycles:** August 2008 and Oct 2008

16

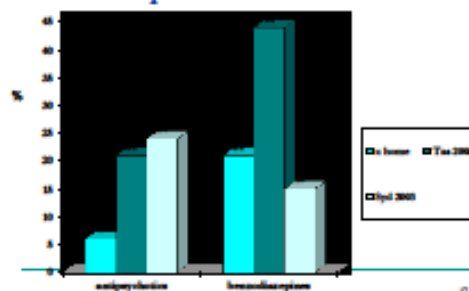
### The DUE cycle ([www.nps.org.au](http://www.nps.org.au))

2017 A shared approach  
Positive health outcomes for the community



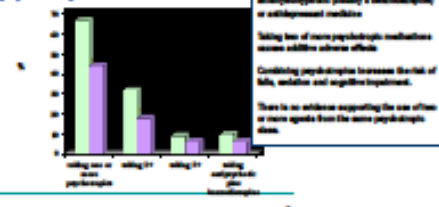
17

### What is the pattern of antipsychotic and benzodiazepine use in .....?



18

### What was your use of multiple psychotropic medications?



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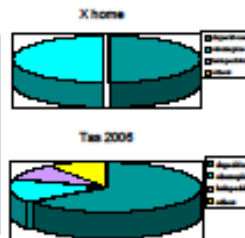
## Which antipsychotics were used?

Manage underlying causes of behaviour and try behavioural strategies first

Use an antipsychotic only if symptoms cause severe distress or risk of harm

- There is no evidence that any drug is more effective than another. Risperidone causes less movement disorders than haloperidol and is PMS listed

Review the need for therapy within 3 months. Withdrawing a antipsychotic may not worsen behaviour



## What benzodiazepines are used?



- Manage underlying causes of sleep disturbance or anxiety and improve sleep hygiene by behavioural strategies first

- In general, if a benzodiazepine is required, initiate treatment with half the recommended dose for younger patients, titrate slowly, and prescribe for short periods

2 weeks for sleep disturbance and 4-6 weeks for anxiety

- Avoid use in patients with known or suspected sleep apnoea as benzodiazepines can contribute to upper airway obstruction during sleep

- Encourage long term users to trial dosage reduction

## Which antidepressants are used?

X home



Tricyclic antidepressants are not recommended for use in older people due to a high risk of side effects such as confusion, sedation, heart beat irregularities, dry mouth, constipation and urinary hesitancy

In many cases low dose tricyclic antidepressants such as amitriptyline and doxepin are used to treat incontinence, sleep disturbance and neuropathic pain

There are alternatives to tricyclic antidepressants for treating non-mental health conditions

## Sedative Review

**RedUse**

Review of sedative use

NAME: [ ] SURNAME: [ ] DATE: [ ]

REASON FOR REVIEW: [ ]

REVIEWER: [ ]

REVIEW DATE: [ ]

REVIEW RESULTS: [ ]

REVIEW COMMENTS: [ ]

REVIEW SIGNATURE: [ ]

REVIEW DATE: [ ]

## How to Reduce sedatives?

- When long-term benzodiazepines are stopped suddenly, withdrawal symptoms occur in about 40% of people. (e.g. insomnia, anxiety, tremour...)

To avoid withdrawal symptoms:

reduce the dose slowly by 10-20% every few weeks

- ensure reduction schedule is flexible
- consider changing benzodiazepine to diazepam which is easier to reduce slowly

Antipsychotics should be reduced gradually by halving the dose every 2 weeks




Thank you

Funded by the Australian Government Department of Health and Ageing

— as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia.



## Sample page from 'RedUSER' newsletter



UTAS  
FACULTY OF  
HEALTH SCIENCE  
School of Pharmacy

the

# RedUSER

## Reducing Use of Sedatives

THE REDUSER,  
DECEMBER 2008  
EDITION 2

### In this edition.....

- First Drug Use Evaluation results
- The DART-AD trial
- RedUSE feature medication: "Olanzapine"
- Exercise: can it help dementia?
- Latest RedUSE news...

### First Drug Use Evaluation (D.U.E) Results

The first Drug Use Evaluation (DUE) results for the RedUSE project were collected during August and September 2008.

DUEs are clinical audits of medication use and are recommended by the National Prescribing Service in aged care homes.

DUE results can be compared

to results from other homes or recent studies; a process known as 'benchmarking'.

The RedUSE D.U.E. focuses primarily on benzodiazepines and antipsychotics and compares the overall use of these two medication groups to other homes in the project as well as to Central Sydney.

The chart below shows the benzodiazepine rates of use for each RedUSE home. The graph shows a large variation between RedUSE homes in the use of these medications.

RedUSE Hobart aged care homes- BENZODIAZEPINE use

Home Code	Proportion of residents (%)
1	17
2	21
3	26
4	27
5	28
6	30
7	31
8	31
9	33
10	35
11	36
12	44
13	47

### DART-AD trial

A recent UK trial<sup>1</sup> (DART-AD) aimed to determine the impact of long-term treatment of anti-psychotics upon behavioural symptoms and overall decline in patients with Alzheimer's disease.

Over one hundred patients with behavioural symptoms taking antipsychotics for longer than 3 months were randomly assigned to two groups. The first group continued anti-psychotics for 12 months whereas the other group

was switched to placebo (inactive treatment).

The researchers found that withdrawal of antipsychotic treatment had no significant effect on function, behaviour or cognition. There was, however, a significant deterioration in verbal fluency for those patients continuing antipsychotic treatment.

1 Ballard C et al. A Randomized, Blinded, Placebo-Controlled trial in Dementia Patients continuing or stopping neuroleptics. (DART-AD) *PLoS Medicine* 2008; 5(4) e76

### General principles when reducing sedative medication:

- Antipsychotics should be reduced gradually by halving the dose no more frequently than every two weeks
- Withdrawal of benzodiazepines must be gradual with a reducing regime generally taking 6-8 weeks
- Gradually reduce the resident's benzodiazepine dose using a set reducing dosage over a set time period (e.g. reduce the most important dose of the day by ¼ of a tablet)
- Discuss sleep, stress management and exercise strategies and provide encouragement.

Page from Relative information leaflet



**Other ways of tackling anxiety and sleeping problems**

Benzodiazepines are not recommended for long term use for anxiety and sleep problems. There may be other ways of tackling symptoms of anxiety; for example, relaxation tapes or talking about underlying causes. If anxiety symptoms persist or are severe, the doctor may advise on other treatments.

As people age, their sleep pattern often changes. Older people require less sleep than younger people. Measures such as keeping more active during the day, participating in activities provided by the home and avoiding caffeine drinks such as tea and coffee in the late afternoon and evening may promote natural sleep.

*2008. Juanita Westbury MSc, BPharm, RedUSE Project Manager, UMORE 6226 1966*

**The RedUSE project is funded by the Australian Government Department of Health and Ageing – as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia**

## Sedative Review Plan

## Sedative Review Plan



Please write comments on how to best reduce the use of sedatives in this patient.

**Patient name: Rod Flanders Residential Care Facility: My Nursing Home 1**

**GP Details: Dr. Julius Hibbert**

Fax: 6249 9035

Phone:

Date	Drug Name	Instructions	Total Daily Dose	Date of First Supply
3/07/2008	Alodorm 5mg Tab	Take ONE and a HALF tablets at night	7.5 mg	
3/07/2008	Risperdal 0.5mg Tab	Take ONE tablet at night	0.5 mg	18/06/2007

Pharmacist's  
Comments

..... Now give to the patient's Nurse for the RN comments

RN's  
Comments

..... Now give to patient's GP for their comments

Doctor's  
Comments

..... Now store this form in the patient's notes at the Residential Home, and review regularly

## Economic Analysis Report

### ECONOMIC DIMENSIONS OF REVIEW OF SEDATIVE USE IN AGED CARE

#### 1. Introduction

The broader research objectives and methodology for the main project have been outlined in the main report in some detail. As part of the main study into sedative use in aged care, it was decided to have a preliminary look at the relevant economic issues.

It was never intended that there would be a detailed examination of all the economic drivers in this investigation. This was in part because, by application of benefit:cost principles, it was concluded that it was not worth undertaking a detailed examination unless the perceived benefits significantly exceeded the costs.

Initial feelings of researchers were that non economic outcomes rather than economic ones, were most likely from a better adherence to best practice prescribing policy for sedatives in aged care. By this is meant that improved health care and patient well-being were likely to be far more important than cost savings from reduced sedative consumption in the average Australian nursing home.

Accordingly, in the design of the research project, financial and economic issues have not been at the forefront. However, having said this, significant information was collected to enable some critical but albeit limited economic analysis to be undertaken.

#### 2. Broad Approach

It is appropriate to apply a benefit:cost type assessment as to whether the apparent findings of the RedUSE project justify a widespread adoption in the Australian nursing homes (or wider) population – or whether further detailed research, as proposed in the conclusion of the main study, should occur before that action is considered further.

Such an approach requires:

- (a) identification of relative “benefits” and “costs” – from a substantial reduction in sedative consumption in nursing homes;
- (b) attribution of a financial measure, if possible, to each of the benefits and costs;
- (c) a comparison of the total benefits and costs and, if the benefits are significantly greater than the costs, there are grounds for pursuing mechanisms to reduce sedative consumption in nursing homes.

#### 3. Specific Identification of Benefits and Costs

The following are the primary “benefits” that might be expected from significant compliance with best practice prescribing of sedatives in nursing homes – as compared with the current practice of prescribing sedatives - which is significantly higher than best practice policy:

- (a) less patient falls – and hence potentially less patients needing more expensive treatment and hence higher health costs;
- (b) better health of patients – by a feeling of greater engagement within their community; and
- (c) less cost for medicines – due to either no consumption at a individual patient level or a lesser consumption of sedatives in nursing homes generally.

The following are the primary “costs” that might be expected from a significant compliance with best practice prescribing of sedatives in nursing homes:

- (i) the time for education of health professionals – in terms of reading materials and attending training courses on optimal sedative consumption;
- (ii) software costs – as a result of preparation and installation of software used in the RedUSE program; and
- (iii) the time for data entry into a personal computer and review – as part of the RedUSE program.

A comment on the most likely financial magnitude of each of the above six elements is shown below:

- (a) less patient falls - insufficient data on reductions in falls with lower sedative use at this stage – and hence very difficult to put a financial figure on this at this stage;
- (b) better health- very difficult to assess – and even harder to ascribe a financial figure to;
- (c) less medicine costs- see next section;
- (i) time for education- expected to be small and perhaps could be considered part of the normal education or up-skilling processes;
- (ii) software- cost would be minimal – as most research and development is already complete;
- (iii) time for data entry- is expected to be minimal – and could be considered part of normal patient care activities.

#### 4. Actual Results

In broad terms, the conclusions reached by the clinical researchers was that the RedUSE program could generate a significant reduction in the use of sedatives in nursing homes – as compared with current consumption rates.

The main results, from a cost of medicines perspective, are shown in Tables 1 and 2. Table 1 shows the costs of antipsychotics and Table 2 shows use of benzodiazepines.

	Control		Intervention	
	Week = 1-4	Week = 23-26	Week = 1-4	Week = 23- 26
Number of residents	684	705	891	888
Total cost of sedative medicines for patients per month (30 days)	\$11,452	\$12,339	\$12,630	\$12,849
Average cost per patient for medicines per month (30 days)	\$16.74	\$17.50	\$14.18	\$14.47



Table 1 – Details of antipsychotic consumption during the 6 months study.

	Control		Intervention	
	Week = 1-4	Week = 23-26	Week = 1-4	Week = 23 26
Number of residents	684	705	891	888
Total cost of sedative medicines for patients per month	\$2,007	\$2,377	\$3,434	\$2,886
Average cost per patient per month	\$2.93	\$3.37	\$3.85	\$3.25

Table 2 – Details of benzodiazepine consumption during the 6 months study.

These Tables show, in broad terms, that:

- (a) there was a “control” group (which was in Launceston) and an “intervention” group (which was in Hobart);
- (b) there were two types of sedatives examined; antipsychotics and benzodiazepines (which represents the main groups of sedatives currently in use in Australian nursing homes);
- (c) there was identification of medicine use (and hence costs) at the start of the trial (weeks = 1-4) and at the end of the trial (weeks = 23-26).

Some particular conclusions can be extracted from an examination of Table 1 dealing with antipsychotics. These are as follows:

- A – resident numbers changed slightly over the course of the 26 weeks;
- B – average costs per patient increased slightly in both the control group (4.5%) and the intervention group (2%) over the course of the 26 weeks;
- C – costs in the intervention group were significantly lower (15%) than in the control group at the start of the trial.

Some particular conclusions can be extracted from an examination of Table 2 dealing with benzodiazepines. These are as follows:

- D. – resident numbers have changed slightly over the course of the 26 weeks (same as for Table 1);
- E. – costs per patient increased significantly in the control group (15%) over the course of the 26 weeks
- F. – average costs per patient decreased significantly in the intervention group (15%) over the course of the 26 weeks
- G. - costs in the intervention group were significantly higher (31%) than in the control group at the start of the trial.

## 5. Actual Results of Main Trial

The primary study demonstrated that, by adopting a multidisciplinary approach, led by a community pharmacist involving nursing staff and promoting GP and resident/relative involvement, there can be a significant reduction in the use of sedatives towards best practice consumption levels.

Whilst the full details can be extracted from the primary report, in short, in a sample of nursing homes in southern Tasmania, following the intervention strategy designed and delivered over a 6 month period– as compared with a legitimately constructed and comparable control group:

- (a) there was a 16% overall reduction in the regular taking of benzodiazepines (from 32% to 27%);
- (b) there was 9% overall reduction in antipsychotic use (from 20.3% to 28.6%);
- (c) there was a 22% increase in dose reductions/cessations of benzodiazepines and (this represented a more than doubling of reductions/cessations);
- (d) there was a 16% increase in dose reductions/cessations of antipsychotics. (again there were double the numbers of agents reduced/ceased).

## 6. Discussion

As identified above, there was not intended to be a complete and detailed assessment of the costs and benefits of the trial – but there was intended to be the basis for intelligent assessment of future directions necessary in relation to economic analysis.

Accordingly, a number of areas where the study is not ideal for economic assessments can be identified. For instance, the data collected on costs is not directly comparable – as there is a change in the sample size over the period being assessed. The tracking of the same patients for the whole trial would also have been preferable to group averages for the purpose of economic analysis.

Another issue of concern is that the average costs of medication in the “control” and “intervention” groups were not similar at the start of the trial. It would seem that this is due to variation in prescribing habits from area to area. Hobart was prone to use much cheaper antipsychotics but more expensive benzodiazepine agents. Every area has its own prescribing patterns. This situation requires further examination. In addition, it is difficult to differentiate between the “volume” and “cost” drivers leading to the changes in average costs per patient. (It is understood that there was a significant increase in some medications during the course of the trial. This is not unusual in economic analysis but more analysis is required to disaggregate these effects.)

However, these are not fatal flaws in achieving the primary objective of getting an understanding of the order of magnitude of the various cost and benefit drivers. Indeed, it is clear from this initial analysis that the primary “cost” of introducing the drug reduction strategies are relatively small and the “benefits” – at least in terms of the medicine savings are also small – but still worth doing as there is a positive benefit:cost ratio.

As identified in the main report, more light will be shed on the “benefits” if there can be a better identification of the nexus between falls of patients in nursing in homes and higher sedative prescribing rates and also the nature of better health for patients from a reduction in average sedative use – towards the best practice prescribing levels. (A further study is in progress to examine the impact of the project on falls rates and levels of challenging behaviour within participant homes.)

However it is possible to ascertain that, as compared with an increase of medicine costs by approximately 15% for the control group, the medicine cost fell by approximately 15% for the intervention group. This represents a 30% difference at the end of the trial which is certainly significant.

It would seem that there is some difficulty establishing a common measure for the number of nursing home patients for which there is commonality. Some guidance is provided from the Australian Institute of Health and Welfare: 'Residential aged care in Australia 2006–07: A statistical overview' (June 2008) Cat. no. AGE 56. This report shows that as of 30 June 2007, there were 4,354 "residents of aged care homes" in Tasmania and 170,071 in Australia as a whole.

If therefore an assumption is made that there is a high level of homogeneity of nursing home patients across Australia, it is possible to suggest an extrapolation from the "intervention" group in Tasmania to the Australian population. This requires a calculation to estimate both the current average cost/patient and the potential saving/average patient over a year – say by a reduction in their benzodiazepine medication cost by 15%.

The results from the trial showed that the average resident monthly cost of benzodiazepines was \$3.38 – which works out to 78 cents per week. If this was reduced by 15%, this cost would fall by 11 cents per resident per week. This converts to a potential saving per resident of \$5.72 per year. With almost 6000 residents in Tasmanian ACHs, the total potential savings could approach \$35 000 per annum for the state alone.

## 7. Conclusion

The main study demonstrated that by application of the program, there can be a substantial reduction in sedative use in nursing homes – bringing them much closer to best practice prescribing regimes.

The preliminary economic analysis has indicated that implementation of the program appears cost effective – and consequently more research should be undertaken to refine the potential benefits that can be achieved.

These benefits are more likely to be non financial – but it appears that, given increases in sedative costs, there is still a significant cost saving to be achieved in every State and Territory, and Australia more generally, by implementing the RedUSE program.

# Alarm over sedation of elderly

DAVID KILICK

ELDERLY people in Tasmanian nursing homes are given sleeping tablets at a much higher rate than their counterparts interstate, a new study has found.

Half of the state's nursing-home residents are prescribed benzodiazepines, compared with about one third of residents interstate.

The University of Tasmania is carrying out a project to radically cut benzodiazepine use after research by PhD student Juanita Westbury uncovered the high rate of prescribing.

Professor Gregory Peterson of the university's School of Pharmacy said the use of benzodiazepines was associated with an increased risk of falls and hip fractures and a reduced quality of life.

"There's data from Sydney showing perhaps 35 per cent of residents are on benzodiazepines and in Tasmania it's more like 50 per cent — it's quite a bit higher," he said.

While much of the use of the drugs was medically necessary,



**TOO MUCH:** Gregory Peterson, benzodiazepine prescription in Tasmania is excessive.

“The biggest issue with these sedative drugs is the risk of falls and therefore hip fractures”

they were sometimes over-prescribed.

"It's for sleeping or they are sometimes used perhaps to control behaviour with dementia which they're not really recommended for," Prof Peterson said.

"The idea is to try to improve

practice here — to try to reduce it.

"The biggest issue with these sedative drugs is the risk of falls and therefore hip fractures and therefore quality of life, it's one of the greatest dangers.

"They're well known to be the greatest risk factors in causing falls in older people."

The solution was informing health professionals about different approaches, he said.

"It's largely an educational focus on GPs and nursing home staff and also carers and relatives because there probably is an element of that too where relatives don't want to see their mother or grandmother distressed or with abnormal behaviour or aggressiveness," Prof Peterson said.

Eight researchers will work on an 18-month project to cut the rate at which benzodiazepines are prescribed in the state's nursing homes.

Tasmania dominated the latest round of federal pharmaceutical research funding with four out of 12 projects approved nationwide attracting almost \$720,000.



July 2009

Dear Sister ,

A few weeks ago we sent a letter requesting some data from your Aged Care Home. Your Home has recently participated in the RedUSE (Reducing Use of Sedatives) project which aims to promote the quality use of psychotropic medication in aged care homes.

The researchers are currently analysing the project data to evaluate the effect of the intervention. The research team would like to collect your falls rate data to assess if the project has indeed impacted on this measure. We would also like to collect available data on the incidence of challenging behaviour before and during the RedUse project. The idea behind collecting this information is to gain some measure of the impact of project on resident clinical outcomes.

We are asking you to provide some information to the research team regarding falls and challenging behaviour rates in your aged care home over the last 12 months. If this is acceptable to you, could you please **fax or send** the completed form back to the RedUSE project manager at the School of Pharmacy, University of Tasmania on **6226 7627**. Please note that the researchers will de-identify and code data from each aged care home. The data will only be used for analyses related to this project.

**\*\*\*\*We understand that this data collection will take some effort, so remuneration of a \$100 gift voucher is being offered to each aged care home for your assistance with this project.\*\*\*\*\***

This project has received ethical approval from the Southern Tasmania Health & Medical Human Research and Ethics Committee. If you have any concerns of an ethical nature or complaints about the manner in which the project is conducted, you may contact the Executive Officer of the Tasmanian Human Research Ethics Committee (Tasmania) Network on 62267479 or [human.ethics@utas.edu.au](mailto:human.ethics@utas.edu.au). You will need to quote ethics reference number H9858'

If you have any queries about this request or the RedUSE project please call the project manager, Juanita Westbury or myself on 6226 1966 or email: [Juanita.Westbury@utas.edu.au](mailto:Juanita.Westbury@utas.edu.au).

Yours sincerely,

A handwritten signature in black ink, which appears to read 'Greg Peterson'.

Gregory Peterson  
Professor of Pharmacy  
School of Pharmacy  
University of Tasmania  
Sandy Bay, Tasmania 7001

Juanita Westbury  
RedUSE Project Manager,  
School of Pharmacy  
University of Tasmania  
Sandy Bay, Tasmania 7001

**The RedUSE project is funded by the Australian Government Department of Health and Ageing through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia.**





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***Community Pharmacy promoting appropriate sedative use in Aged Care: the 'RedUSE' project***

**Post project analysis**      Attention:      Juanita Westbury      June 2009

Could you please provide the following information for post analysis of the RedUSE project:

**Name of Home:**

**Name of nursing representative:**

**Signature:**

**Rate information**

**Falls**

**Challenging Behaviours**

Apr 2008:	Number/rate of falls:.....	Number/rate of CBs .....
May 2008:	Number/rate of falls:.....	Number/rate of CBs .....
Jun 2008:	Number/rate of falls:.....	Number/rate of CBs .....
Jul 2008:	Number/rate of falls:.....	Number/rate of CBs.....
Aug 2008:	Number/rate of falls:.....	Number/rate of CBs.....
Sep2008:	Number/rate of falls:.....	Number/rate of CBs.....
Oct 2008:	Number/rate of falls:.....	Number/rate of CBs.....
Nov 2008:	Number/rate of falls:.....	Number/rate of CBs.....
Dec2008:	Number/rate of falls:.....	Number/rate of CBs.....
Jan 2009:	Number/rate of falls:.....	Number/rate of CBs.....
Feb 2009:	Number/rate of falls:.....	Number/rate of CBs.....
Mar 2009:	Number/rate of falls:.....	Number/rate of CBs.....
Apr 2009:	Number/rate of falls:.....	Number/rate of CBs.....

**This information will assist us greatly in our research. Thank you!!!!**

Please return this form to the Tasmanian School of Pharmacy in the **reply-paid envelope** provided or by faxing it to us on **6226 7627**.